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Screening for Gonorrhea and Chlamydia: Systematic Review to Update the U.S. Preventive Services Task Force Recommendations

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Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

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Prepared by:
Pacific Northwest Evidence-Based Practice Center
Oregon Health & Science University
3181 SW Sam Jackson Park Road
Portland, OR 97239
www.ohsu.edu/epc

Investigators:
Heidi D. Nelson, MD, MPH
Bernadette Zakher, MBBS
Amy Cantor, MD, MPH
Monica Deagas, BA
Miranda Pappas, MA

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The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment.

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Structured Abstract

Background: Previous research has supported screening for gonorrhea and chlamydia in asymptomatic sexually active women, including pregnant women, who are younger than age 25 years or at increased risk, but not other patient populations.

Purpose: To update the 2005 and 2007 systematic reviews for the U.S. Preventive Services Task Force on screening for gonorrhea and chlamydia in men and women, including pregnant women and adolescents.

Data Sources: MEDLINE (2004 to June 13, 2014), Cochrane Central Register of Controlled Trials (through May 2014), Cochrane Database of Systematic Reviews (through May 2014), Health Technology Assessment Database (through May 2014), Database of Abstracts of Reviews of Effects (through May 2014), and reference lists.

Study Selection: English-language trials and observational studies about screening effectiveness, test accuracy, and screening harms.

Data Extraction: One investigator extracted data on participants, study design, analysis, followup, and results and a second investigator confirmed key data. Investigators independently dual-rated study quality and applicability using established criteria.

Data Synthesis: Screening a subset of asymptomatic young women for chlamydia in a good-quality trial did not statistically significantly reduce pelvic inflammatory disease over the following year (relative risk, 0.39 [95% CI, 0.14 to 1.08]), while one previous trial reported a reduction. An observational study evaluating a risk prediction tool to identify persons with chlamydia in high-risk populations had low predictive ability and applicability. In 10 new studies of asymptomatic participants, nucleic acid amplification tests demonstrated sensitivity of 86% or greater and specificity of 97% or greater for diagnosing gonorrhea and chlamydia, regardless of specimen type or test.

Limitations: Studies of screening benefits and harms were lacking for men, pregnant women, adolescents, and subgroups. Only screening tests and methods cleared by the U.S. Food and Drug Administration for current clinical practice were included to determine diagnostic accuracy, excluding rectal, pharyngeal, and self-administered specimens obtained outside a clinical setting.

Conclusions: Chlamydia screening in young women may reduce pelvic inflammatory disease. Nucleic acid amplification tests are accurate for diagnosing gonorrhea and chlamydia in asymptomatic persons using various types of specimens. Research is needed on the effectiveness of screening to reduce adverse health outcomes in specific population groups, effectiveness of different screening strategies, and adverse effects of screening to further inform practice guidelines.

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CHAPTER 1. INTRODUCTION

Purpose and Previous U.S. Preventive Services Task Force Recommendation

This report will be used by the U.S. Preventive Services Task Force (USPSTF) to update its 2005 recommendation on screening for gonorrhea[1] and its 2007 recommendation on screening for chlamydia.[2] It focuses on studies published since prior USPSTF systematic reviews of these topics.[3-5] **Appendix A** provides a description of terms and abbreviations used in this report.

In 2005, the USPSTF issued a B recommendation to screen for gonorrhea in all sexually active women at increased risk for infection, including pregnant women.[1] Women at increased risk include those who are younger than age 25 years; live in high prevalence communities; have a history of gonococcal infection or other sexually transmitted infections (STIs); have new or multiple sex partners; or engage in inconsistent condom use, sex work, or drug use. The USPSTF recommended against routine screening in men and nonpregnant women at low risk for infection (D recommendation), and found insufficient evidence to recommend for or against routine screening in high-risk men and low-risk pregnant women (I statement).

In 2007, the USPSTF issued an A recommendation to screen for chlamydia in all sexually active nonpregnant women younger than age 25 years and in older high-risk nonpregnant women (i.e., those who have a history of chlamydial infection or other STIs, have new or multiple sex partners, or engage in inconsistent condom use or sex work).[2] The age specification for screening in the 2007 recommendation differed from the previous recommendation (age ≤25 years) in order to align with evidence on screening, including national surveillance data from the Centers for Disease Control and Prevention (CDC). The USPSTF also recommended screening in pregnant women younger than age 25 years and in older high-risk pregnant women (B recommendation), and recommended against routine screening in low-risk women age 25 years or older regardless of pregnancy status (C recommendation). The USPSTF found insufficient evidence to recommend for or against routine screening in men (I statement).

Condition Definition

Gonorrhea is an STI caused by the bacterium *Neisseria gonorrhoeae*, a gram-negative intracellular diplococcus that infects the mucosal epithelium of the genital tract.[6,7] Other sites of infection include the conjunctiva, oropharynx, and rectum. Infection with *N. gonorrhoeae* often leads to local inflammation and, in women, can ascend the urogenital tract and cause pelvic inflammatory disease (PID).[6] Infants born to infected mothers may contract gonococcal eye disease in the first few days of life.[8]

Chlamydia is an STI caused by the bacterium *Chlamydia trachomatis*. Most *C. trachomatis* strains infect the epithelial cells of the genital tract, causing inflammation that may be asymptomatic or present as erythema, edema, and mucopurulent discharge.[9] Infections of the

rectum can cause proctitis, while infections of the oropharynx are typically asymptomatic. Inflammation damages the epithelium and leads to scar formation. In women, scarring may ultimately lead to fallopian tube occlusion and infertility years after active infection. Infants born to infected mothers may contract chlamydial eye disease and pneumonia.[8,9]

Prevalence

Gonorrhea is the second most commonly reported STI in the United States after chlamydia. In 2012, 334,826 cases were reported to the CDC, although less than half of all cases are actually diagnosed and reported.[10] Prevalence rates among women and men are similar (108.7 vs. 105.8 cases per 100,000, respectively), and the highest rates of infection are among persons ages 15 to 24 years.

Chlamydia is the most commonly reported STI in the United States. In 2012, 1,422,976 cases of chlamydia were reported to the CDC.[10] However, the true incidence of chlamydia is difficult to accurately estimate because most infections are asymptomatic and are therefore undetected. In 2012, the rate of chlamydial infection among women (643.3 cases per 100,000) was more than double the rate among men (262.6 cases per 100,000), with the majority of cases occurring among women ages 15 to 24 years.

Estimates of coinfection with both gonorrhea and chlamydia are not available.

Pregnancy

In 2011, CDC surveillance data indicated that the median State-specific gonorrhea positivity rate among women ages 15 to 24 years screened in selected prenatal clinics in 15 states, Puerto Rico, and the Virgin Islands was 0.8 percent (range, 0.0% to 3.8%), and the chlamydia positivity rate was 7.7 percent (range, 2.8% to 16.3%).[8] The risk for mother-to-child transmission of gonorrhea is between 30 and 47 percent.[11]

Etiology, Natural History, and Burden of Disease

Gonococcal infections in women are often asymptomatic, but can cause cervicitis and complications of PID, such as ectopic pregnancy, infertility, and chronic pelvic pain.[8] Gonorrhea in men can lead to symptomatic urethritis, epididymitis, and prostatitis.[12] The majority of urethral infections in men are symptomatic, resulting in timely treatment that prevents serious complications.[13] However, infections at extragenital sites (i.e., pharynx and rectum) are typically asymptomatic. Rarely, local gonococcal infections disseminate, causing an acute dermatitis tenosynovitis syndrome that can be complicated by arthritis, meningitis, or endocarditis.[7,14] Gonorrhea facilitates HIV transmission in both men and women.[8]

As with gonorrhea, chlamydial infections in women are usually asymptomatic, but can cause cervicitis and urethritis.[15] Ten to 15 percent of untreated chlamydial infections progress to symptomatic PID that can cause infertility, chronic pelvic pain, and ectopic pregnancy.[8,15]

Genital chlamydial infection in men is usually asymptomatic, but can cause nongonococcal urethritis, epididymitis, and, in rare instances, uretheral strictures and reactive arthritis.[8,16] Chlamydia can also infect nongenital sites and can facilitate the transmission of HIV infection.[8,17,18]

Risk Factors

Age is a strong predictor of risk for both gonorrhea and chlamydia. In 2012, rates of gonococcal infection reported to the CDC were highest among women ages 20 to 24 years (578.5 cases per 100,000), women ages 15 to 19 years (521.2 cases per 100,000), and men ages 20 to 24 years (462.8 cases per 100,000). Rates of chlamydial infection were also highest among women ages 20 to 24 years (3,695.5 cases per 100,000), women ages 15 to 19 years (3,291.5 cases per 100,000), and men ages 20 to 24 years (1,350.4 cases per 100,000).[10]

Infection rates vary by race and ethnicity. In 2012, rates of gonococcal infection among blacks (462.0 cases per 100,000), American Indians/Alaska Natives (124.9 cases per 100,000), Native Hawaiians/Other Pacific Islanders (87.8 cases per 100,000), and Hispanics (60.4 cases per 100,000) were higher than among whites (31.0 cases per 100,000) and Asians (16.9 cases per 100,000). The rates of chlamydial infection among blacks (1,229.4 cases per 100,000), American Indians/Alaska Natives (728.2 cases per 100,000), Native Hawaiians/Other Pacific Islanders (590.4 cases per 100,000), and Hispanics (380.3 cases per 100,000) were also higher than among whites (179.6 cases per 100,000) and Asians (112.9 cases per 100,000).[10]

Infection rates are high among specific population subgroups. Among men who have sex with men (MSM) tested at 42 STI clinics in 12 local and state health jurisdictions during 2012, the median gonorrhea prevalence rate was 16.4 percent (range, 9.8% to 30.4%), and the chlamydia prevalence rate was 12.0 percent (range, 6.4% to 22.2%).[10] Among men and women enrolled in the National Job Training Program, a program for socioeconomically disadvantaged youth ages 16 to 24 years, median prevalence rates for chlamydia in 2012 were 11.0 percent (range, 5.5% to 19.4%) in women and 7.0 percent (range, 0.6% to 13.5%) in men.[10] Prevalence rates for gonorrhea were 1.3 percent (range, 0.0% to 4.8%) in women and 0.7 percent (range, 0.0% to 2.8%) in men. Among adolescents entering selected juvenile correctional facilities in 2011, prevalence of gonorrhea ranged from 0.1 to 4.9 percent and from 5.4 to 17.3 percent for chlamydia.[8] Prevalence rates were generally higher among women than men for both infections.

Other risk factors include having new or multiple sex partners or a partner with an STI, inconsistent condom use, and history of previous or coexisting STIs.[3,4]

Rationale for Screening and Screening Strategies

Gonorrhea and chlamydia are often asymptomatic in infected women, but can cause serious complications[10] and be transmitted to sex partners and unborn children. Screening has the potential to improve the detection and treatment of infected individuals and reduce the severity of complications of untreated disease and transmission. The two infections have comparable

distributions in populations and can be detected using similar tests from the same specimen. The availability of accurate screening tests and effective treatments make screening a feasible approach.

Interventions and Treatment

Infection with *N. gonorrhoeae* can be detected by nucleic acid amplification tests (NAATs) using male and female urine and clinician-collected endocervical, vaginal, and male urethral specimens.[10] Most NAATs cleared for use on clinician-collected vaginal swabs are also cleared for use on self-collected vaginal specimens obtained in clinical settings. Rectal and pharyngeal swabs can be collected from persons who engage in receptive anal and oral intercourse, although these sites of collection have not been cleared by the U.S. Food and Drug Administration (FDA). Gonorrhea can also be detected by culture, which is recommended for diagnosing resistant strains and for detecting strains with decreased antimicrobial susceptibility. Antimicrobial susceptibility testing can only be performed using culture.

Current recommendations support using NAATs to detect *C. trachomatis* infections because their sensitivity and specificity are high and they have been cleared by the FDA for use on urogenital sites, including male and female urine, as well as clinician-collected endocervical, vaginal, and male urethral specimens.[10] Most NAATs cleared for use on vaginal swabs are also cleared for use on self-collected vaginal specimens obtained in clinical settings. Rectal swabs can be collected from persons who engage in receptive anal intercourse, although this site of collection has not been cleared by the FDA.

Gonorrhea and chlamydia respond to antibiotic treatment. In recent years, treatment of gonorrhea has been complicated by increasing drug resistance. For nonpregnant adults, new recommendations have replaced the use of oral cephalosporins with a single intramuscular dose of ceftriaxone in combination with either single-dose azithromycin or 7-day doxycycline for the treatment of uncomplicated gonorrhea of the cervix, urethra, and rectum.[19] Combination therapy is recommended to prevent the development of further drug resistance, as well as to treat commonly coexisting chlamydia. Azithromycin is generally preferred to doxycycline as the secondary drug in gonorrhea combination treatment because of its convenience as a single-dose therapy, as well as evidence of gonorrhea resistance to tetracyclines such as doxycycline. Chlamydia is treated with single-dose azithromycin or 7-day doxycycline.[13] In patients for whom adherence or followup is a concern, azithromycin is the preferred choice because it provides a single dose of directly observed treatment.

For patients with either gonorrhea or chlamydia, all sex partners from the preceding 60 days should be evaluated and treated for infection.[13,15,19] Expedited partner therapy is a means of treatment in which medication or a prescription is delivered to the partner by the patient, a disease investigation specialist, or a pharmacy.[19] In the case of treatment for gonorrhea, the partner would receive oral combination therapy with cefixime and azithromycin, rather than intramuscular ceftriaxone. All patients diagnosed with gonorrhea or chlamydia require retesting 3 months after treatment.[13,15]

Pregnancy

Pregnant women infected with gonorrhea require intramuscular ceftriaxone and oral azithromycin.[10,13] Chlamydial infections in pregnant women are treated with single-dose azithromycin or 7-day amoxicillin.[13] In addition, a test of cure to document eradication of chlamydial infection 3 weeks after treatment is recommended. Pregnant women diagnosed with chlamydia or gonorrhea in the first trimester should also be retested 3 months after treatment. Gonococcal neonatal ophthalmia, resulting from transmission from an untreated woman to her newborn, may be prevented with routine topical prophylaxis at delivery. However, prevention of chlamydial neonatal pneumonia and ophthalmia require prenatal detection and treatment.

Current Clinical Practice

Despite current guidelines that recommend screening for gonorrhea and chlamydia in high-risk persons, a review of the health care claims of 4,296 men and women presenting for general medical or gynecological examinations from 2000 to 2003 found that almost none had codes for screening for HIV, syphilis, gonorrhea, or chlamydia, regardless of their high-risk sexual behavior status.[20] Among patients claiming high-risk sexual behaviors, only 21 to 56 percent were tested for gonorrhea and 21 to 60 percent were tested for chlamydia. Similarly, a review of the U.S. Healthcare Effectiveness Data and Information Set from 2000 to 2007 showed a 64.4 percent increase in testing for chlamydia among young, sexually active women enrolled in commercial and Medicaid health plans during that period; however, the testing rate in 2007 was only 41.6 percent.[21] Population-based survey data from 2005 to 2008 in the United States indicated that many pregnant women were not tested, and followup testing was not always performed.[22]

Recommendations of Other Groups

The CDC's recommendations are similar to those of the USPSTF and include targeted screening for gonorrhea and chlamydia in women at increased risk, while screening in other groups, including men, is not recommended.[1,2,13] The CDC also advises screening in other selected high-risk populations, including MSM and young women in juvenile detention or jail facilities. Recommendations from the CDC and other professional groups are summarized in **Table 1**.

CHAPTER 2. METHODS

Key Questions and Analytic Framework

This review followed a standard protocol consistent with the Agency for Healthcare Research and Quality's (AHRQ's) methods for systematic reviews.[23,24] Based on evidence gaps identified from prior reviews,[3-5] the USPSTF and AHRQ determined the scope and Key Questions of the review. A research plan was externally reviewed and modified. Investigators created two analytic frameworks incorporating the Key Questions and outlining the patient populations, interventions, outcomes, and potential adverse effects. The first analytic framework is for asymptomatic, sexually active men and nonpregnant women, including adolescents (**Figure 1**). The second analytic framework is for pregnant women (**Figure 2**).

The review includes studies published since prior USPSTF reviews of these topics.[3-5] Studies were included if they were applicable to clinical settings and practices in the United States, as determined by the similarity of participants and health care services to real-world situations and the use of screening tests that are available and FDA-cleared for clinical use. The conditions of interest are gonococcal and chlamydial infections in asymptomatic persons.

The Key Questions for men and nonpregnant women are:

1. How effective is screening for gonorrhea and chlamydia in reducing complications of infection and transmission or acquisition of disease in asymptomatic, sexually active men and nonpregnant women, including adolescents?
2. How effective are different screening strategies in identifying persons with gonorrhea and chlamydia?
3. How accurate are screening tests in detecting gonorrhea and chlamydia?
4. What are the harms of screening for gonorrhea and chlamydia?

The Key Questions for pregnant women are:

1. How effective is screening for gonorrhea and chlamydia in reducing maternal complications, adverse pregnancy and infant outcomes, and transmission or acquisition of disease in asymptomatic pregnant women?
2. What are the harms of screening for gonorrhea and chlamydia in asymptomatic pregnant women?

Search Strategies

The investigators worked with a research librarian to conduct searches of electronic databases, including MEDLINE (2004 to June 13, 2014), Cochrane Central Register of Controlled Trials (through May 2014), Cochrane Database of Systematic Reviews (through May 2014), Health Technology Assessment Database (through May 2014), Database of Abstracts of Reviews of Effects (through May 2014), and clinicaltrials.gov (through May 2014) (search strategies are

available in **Appendix B1**). Search dates were selected to update prior USPSTF systematic reviews of these topics. In addition, investigators manually reviewed reference lists of relevant articles.

Study Selection

Abstracts were selected for full-text review if they included asymptomatic, sexually active men and women, including pregnant women and adolescents; were relevant to a Key Question; and met additional prespecified inclusion criteria for each Key Question. Although this update was intended to evaluate studies published since prior USPSTF reviews, the scope, Key Questions, and inclusion criteria differ across reviews, resulting in the inclusion of some apparently older studies that had not been previously reviewed. Two reviewers independently evaluated each study to determine its inclusion eligibility based on prespecified inclusion and exclusion criteria developed for each Key Question (**Appendix B2**). Non-English–language articles and studies published as abstracts were not included.

Studies of screening effectiveness (Key Questions 1 and 2 for general populations and Key Question 1 for pregnant women) were included if they compared health outcomes of screened and nonscreened asymptomatic persons. Outcomes included reduced complications of gonococcal or chlamydial infections and reduced transmission or acquisition of disease, and for pregnant women, reduced maternal complications, adverse pregnancy outcomes, and adverse infant outcomes. Only randomized, controlled trials (RCTs) and controlled observational studies were included to evaluate the effectiveness of screening. Studies of screening strategies were included if they described the study population (number screened, sex, age range, setting, and absence of symptoms), features of the screening program (duration, type of strategy, and followup), and outcome measures. Inclusion criteria for effectiveness studies were less restrictive than for diagnostic accuracy studies because the main comparison concerned outcomes related to the overall approach of screening versus not screening, not the individual tests themselves. Uncontrolled observational studies were included to determine adverse effects of screening (Key Question 4 for general populations and Key Question 2 for pregnant women).

Studies of diagnostic accuracy (Key Question 3) were included if they evaluated the performance of tests in asymptomatic persons using technologies and methods cleared by the FDA and available for clinical practice in the United States. Based on these criteria, rectal, pharyngeal, and self-collected vaginal specimens obtained in nonclinical settings, as well as point-of-care or in-house tests, were excluded. Tests that were previously cleared by the FDA and subsequently removed from the U.S. market were also excluded.[25] Included studies of diagnostic accuracy used credible reference standards, described the study population (number screened, sex, age range, setting, and absence of symptoms), defined positive screening test results, and reported performance characteristics (sensitivity, specificity, positive and negative predictive values, positive and negative likelihood ratios) or provided data to calculate them.

The selection of studies is summarized in **Appendix B3**. **Appendix B4** lists studies excluded at the full-text level with reasons for exclusion.

Data Abstraction and Quality Rating

One investigator abstracted details about study design, patient population, comparison groups, setting, screening method, analysis, followup, and results. A second investigator reviewed data abstraction for accuracy. By using prespecified criteria developed by the USPSTF for RCTs, cohort, and diagnostic accuracy studies,[24] two investigators independently rated the quality of studies (good, fair, or poor) and resolved discrepancies by consensus (**Appendix B5**).

Data Synthesis

Two independent reviewers assessed the internal validity (quality) of new studies for each Key Question using methods developed by the USPSTF, based on the number, quality, and size of studies; consistency of results between studies; and directness of evidence.[23,24] Statistical meta-analysis was not performed because of methodological limitations of the studies and heterogeneity in study designs, interventions, populations, and other factors. Studies included in prior reviews were reviewed for consistency with current results; however, lack of studies and differences in scope, Key Questions, and inclusion criteria limited aggregate synthesis with the updated evidence.

External Review

The draft report was reviewed by six content experts and scientists at the CDC during October 2013 and by USPSTF members, AHRQ Project Officers, collaborative partners, and the public during May 2014 (**Appendix B6**).

Response to Public Comments

This systematic review was posted for public comment from April 29 to May 26, 2014. The investigators reviewed and considered relevant comments. No comments identified missing studies that met inclusion criteria or errors in the evidence reviewed, resulting in no changes to the findings or the conclusion of this report.

CHAPTER 3. RESULTS

Men and Nonpregnant Women, Including Adolescents

Key Question 1. How Effective Is Screening for Gonorrhea and Chlamydia in Reducing Complications of Infection and Transmission or Acquisition of Disease in Asymptomatic, Sexually Active Men and Nonpregnant Women, Including Adolescents?

Summary

No studies of screening for gonorrhea met inclusion criteria for the prior USPSTF reviews or this update. One study of the effectiveness of screening for chlamydia met inclusion criteria. The Prevention of Pelvic Infection (POPI) trial reported a nonstatistically significant reduction in incident PID among asymptomatic, sexually active young women screened for chlamydia compared with unscreened women (relative risk [RR], 0.39 [95% CI, 0.14 to 1.08])[26] (S Kerry, written communication, May 2013).

The 2001[3] and 2007[5] USPSTF reviews on screening for chlamydia identified two trials of screening in women at increased risk for chlamydia (**Table 2** and **Appendix C1**).[27,28] PID was statistically significantly reduced among women screened in a good-quality RCT of young women recruited from a health maintenance organization in the United States (RR, 0.44 [95% CI, 0.20 to 0.90]).[27,28] Reductions were of borderline statistical significance in a poor-quality RCT of Danish students (RR, 0.50 [95% CI, 0.23 to 1.08]).[27,28]

Evidence

Gonorrhea. No effectiveness studies of screening for gonorrhea met inclusion criteria for this update or for prior USPSTF reviews.

Chlamydia. One new RCT of screening for chlamydia in women, but none in men, met inclusion criteria for this update. The POPI trial was a good-quality RCT of 2,529 sexually active young women (mean age, 21 years [range, 16 to 27 years]) recruited from universities and colleges in the United Kingdom (**Appendixes C1** and **C2**).[26] Participants were randomized to screening or deferred groups (considered unscreened), completed questionnaires, and provided self-collected vaginal swabs. Swabs from the screening group were immediately tested for chlamydia, while those from the deferred group were stored and tested 1 year later. Infected women were contacted and referred to their local clinic for treatment and partner notification. After 1 year, participants completed questionnaires about symptoms of PID and sexual behavior during the previous year (94% followup overall). Medical records of women suspected of having PID based on their questionnaire responses were obtained and reviewed by three blinded genitourinary physicians for diagnostic confirmation.

The published results of the trial provided RR estimates for developing PID during followup for

symptomatic (35%) and asymptomatic (65%) participants combined (RR, 0.65 [95% CI, 0.34 to 1.22]).[26] Since asymptomatic women are the focus of this Key Question, the trial investigators provided additional estimates for this subgroup upon request. Among a subgroup of participants who reported no symptoms during the 6 months before the study (i.e., pelvic pain, dyspareunia, abnormal vaginal bleeding or discharge), 0.6 percent (5/787) of the screened group versus 1.6 percent (14/861) of the control group developed PID during followup (RR, 0.39 [95% CI, 0.14 to 1.08]) (S Kerry, written communication, May 2013).

In this trial, 79 percent (30/38) of PID cases overall occurred in women who tested negative at baseline. In addition, 22 percent of participants were tested for chlamydia independently during followup (23% and 22% of the screened and deferred groups, respectively). More women in the deferred group who tested positive for chlamydia had independent testing versus those who tested negative.

The 2001[3] and 2007[5] USPSTF reviews on screening for chlamydia identified two trials of the effectiveness of screening for prevention of PID in nonpregnant women (**Table 2**). A good-quality RCT of 2,607 women at increased risk for chlamydia in a health maintenance organization in Washington state reported a statistically significant reduction in PID in the screened versus usual care group after 1 year of followup (RR, 0.44 [95% CI, 0.20 to 0.90]).[27] In this trial, women randomized to screening were tested in study clinics. A poor-quality RCT of 1,761 female high school students in Denmark found that one-time, home-based screening compared with usual care (opportunistic physician-based screening) was associated with lower incidence of chlamydia (RR, 0.45 [95% CI, 0.24 to 0.84]) and PID (RR, 0.50 [95% CI, 0.23 to 1.08]) after 1 year of followup.[28] Since few participants were actually screened in the usual care group, they were considered to be similar to an unscreened comparison group.

Key Question 2. How Effective Are Different Screening Strategies in Identifying Persons With Gonorrhea and Chlamydia?

Summary

No studies compared the effectiveness of different screening strategies for gonorrhea or chlamydia in asymptomatic persons or the effectiveness of sampling from various anatomical sites, cotesting for concurrent STIs, or using different screening intervals. Several studies of screening in high-risk groups have been published, but they did not meet inclusion criteria because they enrolled both symptomatic and asymptomatic persons, lacked comparison groups, or did not report relevant outcomes. An observational study in the Netherlands evaluated a risk prediction tool to identify persons with chlamydia in high-risk populations.[29] However, the tool was not an accurate predictor, and its applicability to practice in the United States is unclear. Prior reviews did not directly address the effectiveness of different screening strategies, but rather summarized risk factors associated with gonococcal and chlamydial infections.[3,4] An observational study comparing nine sets of selective screening criteria for chlamydial infection among women attending family planning and STI clinics in the United States[30] indicated that age alone had similar or better sensitivity and specificity as more extensive criteria. In this study, nearly 80 percent of cases were identified when testing 50 percent of the population and using an age cutoff of 22 years or younger.

Evidence

An observational study conducted in the Netherlands evaluated a risk prediction tool to identify persons with chlamydia in high-risk populations (**Appendixes C3** and **C4**).[29] Screening criteria were developed on the basis of questionnaire responses from sexually active participants who were subsequently tested for chlamydia and included items on age, education, ethnicity, lifetime sex partners, and condom use. When applied to two high-risk populations, this risk tool was not an accurate predictor of infection (area under the receiver operating curve, 0.66 and 0.68, respectively). The applicability of this study to U.S. populations is also limited.

Key Question 3. How Accurate Are Screening Tests for Detecting Gonorrhea and Chlamydia?

Summary

Ten new fair-quality diagnostic accuracy studies reporting test characteristics of FDA-cleared NAATs met inclusion criteria, including six for gonorrhea and eight for chlamydia. Most studies evaluated the performance characteristics of NAATs compared with culture or expanded reference standards in asymptomatic persons in high prevalence (>5%) settings. Studies reporting the lowest values had important methodological limitations.

For gonorrhea, test sensitivity ranged from 90 to 100 percent in studies without major limitations, and specificity was greater than 97 percent across all specimens and tests. For chlamydia, test sensitivity ranged from 86 to 100 percent in studies without major limitations, and specificity was greater than 97 percent across all specimens and tests. In women, NAATs showed little variation across endocervical, clinician- and self-collected vaginal, and urine specimens. In men, urine specimens had slightly higher sensitivity than urethral specimens.

The prior reviews reported similar findings, but included several studies of non-NAAT tests, including some that are not currently available, as well as studies of symptomatic persons.[3,4]

Evidence

This review focused on the performance characteristics of screening tests in asymptomatic persons compared with either culture or expanded reference standards (i.e., positive result on two nonculture tests, positive result on two different specimens, or positive result on the original test and a confirmatory test). These studies included only FDA-cleared tests and specimen types (**Table 3**).

Ten new fair-quality studies reporting test characteristics of FDA-cleared NAATs met inclusion criteria, including six for gonorrhea (**Appendix C5**)[31-36] and eight for chlamydia (**Appendix C6**).[31-33,36-40] Methodological limitations include unclear descriptions of sampling methods, whether screening tests were interpreted independent of the reference standard,[31-34,37-39] and whether analyses included patients with uninterpretable results (**Appendix C7**).[31,33,34,37,39] Three studies described additional methodological difficulties related to the reference standard[38] and technical approach.[34,37] Most studies reported an infection prevalence of greater than 5 percent

among participants, although rates were lower in three studies.[33,35,36]

Gonorrhea. Test characteristics of NAATs for gonorrhea are provided in **Table 4** for women and **Table 5** for men. All but three studies[33,35,36] reported an infection prevalence of greater than 5 percent among participants. Specificity was high (≥97%) across all studies for men and women regardless of specimen or test.

For women, four studies testing endocervical specimens with transcription mediated amplification (TMA); polymerase chain reaction (PCR), including a new rapid test;[36] or strand displacement amplification (SDA) reported sensitivities ranging from 90 to 100 percent (**Table 6** and **Figure 3**).[33-36] Sensitivity was 98 percent for TMA[35] and 100 percent for PCR[36] using self-collected vaginal specimens obtained in a clinician's office. Results for TMA, PCR, or SDA ranged from 78.6 to 100.0 percent using female urine.[33,34,36] However, the study reporting the lowest sensitivity used urine volumes larger than recommended by the manufacturer of the screening test.[34] When recommended urine volumes were used in a second study, the sensitivity of the same TMA test improved from 78.6 to 95.7 percent.[33]

For men, testing male urethral specimens with SDA and TMA and testing male urine with TMA, SDA, or PCR resulted in similarly high sensitivities across tests in four studies (urethra, 100%; urine, 90% to 100%) (**Table 6** and **Figure 3**).[31,32,34,36]

The 2005 evidence review on screening for gonorrhea reported sensitivity of 90 percent or greater and specificity of 97 percent or greater when cervical specimens were tested with NAATs or nucleic acid hybridization tests.[4] Testing female urine samples with PCR, TMA, or SDA had lower sensitivity (64.8% to 100.0%) than testing cervical specimens, although specificity was high across all specimens and tests. Male urine samples tested with PCR had lower sensitivity than testing urethral specimens, although this difference was not seen with SDA, and specificity was similar between specimen types for both tests. Many of these studies were conducted in high-prevalence populations and included both symptomatic and asymptomatic persons; few reported results by symptom status.

Chlamydia. Test characteristics of NAATs for chlamydia are provided in **Table 7** for women and **Table 8** for men. All but one study[36] reported greater than 5 percent prevalence of infection among participants. Specificity was high (≥96%) across all studies for men and women regardless of specimen or test.

Five studies of endocervical specimens reported sensitivity of TMA ranging from 89.0 to 97.1 percent, sensitivity of SDA ranging from 86.4 to 96.2 percent, and sensitivity of PCR ranging from 86.4 to 95.8 percent (**Table 6** and **Figure 4**).[33,36,37,39,40] Testing clinician-collected vaginal swabs with TMA or PCR resulted in sensitivities of 89.9 and 98.8 percent,[37] respectively, and testing self-collected vaginal swabs obtained in clinical settings resulted in sensitivities of 97.0 percent with TMA[40] and 90.7[37] and 98.0 percent[36] with PCR. Testing female urine samples with TMA, PCR, and SDA resulted in sensitivities ranging from 72.0 to 98.2 percent.[33,36,37,39] Lower sensitivities for testing urine samples with TMA (72%) and PCR (84%) were reported in one study that experienced technical and specimen processing errors.[37]

One study using PCR reported sensitivities that were markedly lower than those in other studies (endocervical, 51.9%; urine, 44.4%; clinician-collected vaginal, 55.6%; self-collected vaginal, 51.9%).[38] This study used a more conservative approach to analysis that only included women with complete sets of results from nine different testing strategies. In addition, the reference standard included positive NAAT results from two separate specimens. When a specimen-specific reference standard was used, as was common in the other studies, sensitivities were comparable with those in other studies (data not provided). Since these data represent outliers resulting from a different method, they are not included in **Figure 4**.

Sensitivities of testing male urethral and urine specimens with TMA, SDA, or PCR were consistently high across four studies, regardless of test, and ranged from 86.1 to 100.0 percent (**Figure 5**).[31,32,36,39]

The 2001 evidence review on screening for chlamydia found that testing endocervical swabs with enzyme immunoassay yielded lower sensitivity (70% to 80%) than PCR (82% to 100%), although specificity was similarly high (≥96%).[3] Testing urine with PCR performed comparably with testing endocervical swabs, and TMA was comparable with PCR. Testing male swab specimens with enzyme immunoassay had an average sensitivity of 80 percent and specificity of 96 to 100 percent, and testing with PCR resulted in higher sensitivity and specificity compared with enzyme immunoassay, similar to results for female specimens. Testing either male swab specimens or urine with PCR or TMA gave comparable performance results. Studies were conducted in high-prevalence populations and combined asymptomatic and symptomatic persons.

Key Question 4. What Are the Harms of Screening for Gonorrhea and Chlamydia?

Summary

New diagnostic accuracy studies without major methodological limitations indicated that false-positive rates for gonorrhea and chlamydia were 3 percent or less, and false-negative rates ranged from 0 to 9 percent for gonorrhea and 0 to 14 percent for chlamydia across all NAATs and specimen types. These results are consistent with prior reviews.[3-5] Several studies of psychosocial harms related to testing, such as anxiety, have been published, but did not meet inclusion criteria because they included symptomatic persons and focused on reactions to positive test results rather than screening itself.

A prior review[5] included results of qualitative interviews about the experience of chlamydia testing from women undergoing opportunistic screening.[41] Although many women felt that screening was beneficial and important, common responses to a positive test result included feeling dirty, ashamed at passing on the infection, and suspicious about the origins of the infection.

Evidence

Gonorrhea. Study results of screening tests for gonorrhea are provided in **Table 4** for women

and **Table 5** for men. False-positive results were uniformly low across studies regardless of test or specimen, ranging from 0 to 2.9 percent. False-negative results had a wider range from 0 to 21.4 percent, although the highest rates can be attributed to studies with important methodological limitations (described previously).

No studies that addressed other harms, such as labeling or anxiety from screening, met inclusion criteria. The 2005 evidence review on screening for gonorrhea indicated similar findings for false-positive and false-negative results and did not address other harms of screening.[4]

Chlamydia. Study results of screening tests for chlamydia are provided in **Table 7** for women and **Table 8** for men. False-positive results were low across all studies regardless of specimen or test, ranging from 0 to 3.6 percent. Most studies of NAATs reported false-negative findings ranging from 0 to 28 percent, although the highest rates can be attributed to studies with important methodological limitations (described previously).[37,38] No studies that addressed other harms, such as labeling or anxiety from screening, met inclusion criteria.

The performance characteristics of chlamydia tests were evaluated in the 2001 review and were similar to this update, although the 2001 review included more studies of non-NAATs. The 2001[3] and 2007 reviews[5] identified no studies of harms of screening for chlamydia, but the more recent review contextually described three qualitative studies of the impact of receiving a positive chlamydia test result.

Pregnant Women

Key Question 1. How Effective Is Screening for Gonorrhea and Chlamydia in Reducing Complications of Infection and Transmission or Acquisition of Disease in Asymptomatic Pregnant Women?

No studies met inclusion criteria for this review as well as for the 2005 review on gonorrhea[4] and the 2007 review on chlamydia.[5] The 2001 review on chlamydia described a time-series and a case-control study predating the review conducted in the 1980s, but identified no new relevant studies.[3]

Key Question 2. What Are the Harms of Screening for Gonorrhea and Chlamydia in Asymptomatic Pregnant Women?

No studies met inclusion criteria, although the rates of false-positive and false-negative results for nonpregnant women are applicable to pregnant women. The prior reviews did not identify any relevant studies.

CHAPTER 4. DISCUSSION

Summary of Review Findings

The USPSTF and other groups currently recommend routine screening for gonorrhea and chlamydia in asymptomatic, sexually active women at increased risk for infection because of age or other risk factors, which is the standard of practice in the United States.[1,2,13,14,42-46] Previous recommendations were based on various levels of evidence indicating that screening provides an opportunity for earlier identification and treatment of infections and reduces adverse health outcomes and transmission.

A summary of evidence for this update is provided in **Table 9**. Only one new trial of the effectiveness of screening for chlamydia in nonpregnant women,[26] one study of a risk prediction instrument,[29] and 10 studies of the diagnostic accuracy of screening tests met inclusion criteria.[31-35,37-40] No studies were available to address several Key Questions. These include the effectiveness of screening for gonorrhea in all population groups and for chlamydia in men, pregnant women, and adolescents; the effectiveness of different screening strategies for identifying persons at increased risk for infection, cotesting for concurrent STIs, and different screening intervals; and harms of screening unrelated to the diagnostic accuracy of tests.

Only one new trial evaluated the effectiveness of screening for chlamydia in nonpregnant women[26] (Key Question 1). In the POPI trial, screening for chlamydia in a subset of asymptomatic young women did not statistically significantly reduce PID over the following year compared with not screening (RR, 0.39 [95% CI, 0.14 to 1.08]). Although it met criteria for good quality, the POPI trial was limited by inadequate recruitment, testing for chlamydia outside of the study protocol during followup in nearly a quarter of participants, and difficulty in ascertaining PID cases. These limitations imply that the study may have been underpowered and the intervention effects attenuated. In addition, most cases of PID occurred in women who tested negative at baseline, suggesting that frequent targeted screening in women at higher risk for infection, including those with new sex partners or recent history of chlamydia, might be more important than one-time routine screening.

Two earlier trials also evaluated incident PID after screening for chlamydia in women at increased risk.[27,28] While a good-quality trial in the United States reported a statistically significant reduction in PID in the screened versus usual care group after 1 year of followup (RR, 0.44 [95% CI, 0.20 to 0.90]),[27,28] reduction in PID was not statistically significant in a poor-quality trial in Denmark comparing one-time, home-based screening with usual care.[27,28] Although all three trials reported point estimates suggesting reduced PID, only the U.S. trial showed a statistically significant reduction. However, this trial met criteria for good quality, was the largest trial, and was the most applicable to clinical practice in the United States.

Additional relevant studies of screening did not meet inclusion criteria because they did not provide results for asymptomatic participants or reported infection rates rather than health outcomes. These studies found no significant improvements in clinical outcomes among those screened for chlamydia, including a large Danish trial of more than 30,000 young men and

women,[47] a retrospective population-based cohort study of more than 40,000 Swedish women,[48] and a register-based screening trial of more than 300,000 men and women in the Netherlands.[49] A time-trend analysis of a U.S. managed care population between 1997 and 2007 indicated an increase in the number of cases of chlamydia in both men and women, but a decrease in PID.[50] It is not clear how screening influenced these outcomes.

The only new study addressing the effectiveness of different screening strategies (Key Question 2) was an observational study evaluating a risk prediction tool to identify persons with chlamydia in high-risk populations.[29] However, it was not an accurate predictor and its relevance to current practice in the United States is uncertain. An older observational study comparing nine sets of selective screening criteria for chlamydial infection among women[30] supports age-based screening in current guidelines, but has not been updated by newer research. Future studies to address this Key Question should compare the effectiveness of screening versus not screening in populations with different levels of risk; use specimens from different anatomical sites; include cotesting for concurrent STIs, including HIV; and evaluate different screening intervals.

Ten studies of the diagnostic accuracy of screening tests met inclusion criteria (Key Question 3).[31-35,37-40,51] The current review differs from prior reviews[3,4] by including only results from asymptomatic participants, which is more clinically relevant to screening populations. Various types of NAATs are highly accurate in diagnosing gonorrhea and chlamydia in asymptomatic persons regardless of specimen, anatomical site, or test.[31-34,37,39,51] Sensitivity was 85 percent or greater and specificity was 97 percent or greater in studies without major methodological limitations, resulting in generally low rates of false-negative and false-positive results. The high accuracy of NAATs reported in these studies is consistent with prior reviews[3,4] and is the basis for the CDC's recommendation on using NAATs for gonorrhea and chlamydia screening.[10]

Several studies of harms (Key Question 4) did not meet inclusion criteria for the update because they focused on the effects of receiving a positive test result, included symptomatic participants, and lacked comparison groups.[52-55] In these studies, persons who tested positive for chlamydia had higher measures of anxiety[52,53,55] and more partner break-ups[52,53] than those who tested negative, who were generally relieved.[53,55]

No studies addressing screening in pregnant women met inclusion criteria, despite the need for additional research in this population. For example, screening in the first trimester may not be sufficient based on findings from an observational study suggesting that chlamydia test results in the first trimester may not predict chlamydia status during the third trimester.[56] Although studies of repeat testing have been conducted in high-risk populations,[57] more research is warranted to further evaluate the value of repeat testing during pregnancy to reduce potential complications, such as preterm delivery and premature rupture of membranes.[58]

Limitations of this review include using only English-language articles, which could result in language bias, though we did not identify non-English–language studies otherwise meeting inclusion criteria in our searches. We only included studies with asymptomatic participants and settings and tests applicable to current practice in the United States to improve clinical relevance for the USPSTF, which excluded much research in the field. Studies were lacking for most Key Questions, and the number, quality, and applicability of studies varied widely. Available

screening trials evaluated only PID as the main outcome, while other outcomes are also important.

NAATs are cleared by the FDA for use on male and female urine, endocervical, and male urethral specimens, and some types of NAATs are cleared for use on clinician- and self-collected vaginal specimens in clinical settings. Studies have also reported comparable test characteristics for nurse- and patient-collected rectal swabs in MSM.[35,37,38,40,59] Additional studies of NAATs using self-collected specimens could provide more evidence for FDA clearance of this technique and increase testing access and acceptability, potentially expanding screening strategies to home-, mail-, or Internet-based screening and encouraging uptake of screening among persons at increased risk.

Limiting our review to FDA-cleared tests excluded studies of rectal and pharyngeal specimens that also demonstrated high accuracy with NAATs,[35,37,38,40,59] which are currently recommended by the CDC.[10] Expanding the range of specimen types for screening has the potential to increase identification of infected persons, especially asymptomatic MSM, in whom nearly 90 percent of all gonococcal infections are at nongenital sites.[60] In this population, NAATs have higher sensitivity at extragenital sites compared with culture, possibly because of lower bacterial loads at the pharynx and rectum.[61,62] In a study of MSM, 85 percent of rectal infections were asymptomatic and only detectable with routine screening.[63] Urethral testing alone missed 84 percent of chlamydial and gonococcal infections compared with 9.8 percent missed by rectal and pharyngeal testing in another study.[60]

In summary, screening for chlamydia may reduce the incidence of PID in young women. Risk prediction tools may be useful in identifying persons with infections, but require validation in the populations of intended use. NAATs are accurate for diagnosing gonorrhea and chlamydia in asymptomatic persons regardless of specimen, anatomical site, or test. Further research is needed to determine the effectiveness of screening in multiple populations and on various clinical outcomes, including but not limited to PID, effective screening strategies, and harms of screening.

Limitations

The review included only English-language articles published since prior USPSTF reviews and does not reflect the total body of evidence on screening for gonorrhea and chlamydia, although relevant earlier studies were referenced. Studies were lacking for most Key Questions, and the number, quality, and applicability of studies varied widely.

This review explicitly focused on asymptomatic populations and included settings and tests applicable to current practice in the United States. While this approach improves its relevance to the USPSTF, it excludes much research in the field. For example, limiting the review to only FDA-cleared tests excluded studies of rectal and throat specimens that also demonstrated high accuracy with NAATs[35,37,38,40,59] and are currently used in practice. This is especially important for screening in asymptomatic MSM, in whom nearly 90 percent of all gonococcal infections are at nongenital sites (throat and rectum).[60]

Emerging Issues and Next Steps

Screening tests for gonorrhea and chlamydia accurately detect infections. In particular, the sensitivity of NAATs has surpassed culture, the former gold standard. NAATs have been cleared by the FDA for use on male and female urine, endocervical, and male urethral specimens, and some types of NAATs are cleared for use on clinician- and self-collected (in clinical settings) vaginal specimens. Studies have also reported comparable test characteristics for nurse- and patient-collected rectal swabs in MSM.[35,37,38,40,59] Additional studies of NAATs using self-collected specimens at various anatomical sites could provide more evidence for FDA clearance of this technique and increase testing access and acceptability. This would expand screening strategies to home-, mail-, or Internet-based screening, and encourage uptake of screening among younger persons at increased risk.

Relevance for Priority Populations

Expanding the range of specimen types for gonorrhea and chlamydia screening has the potential to increase identification of infected persons, particularly among priority populations. For example, the ability to test rectal and pharyngeal specimens may increase detection among MSM. Currently, NAATs are not FDA-cleared for use on rectal or pharyngeal sites in testing for gonorrhea and chlamydia. However, NAATs have improved sensitivity for detecting gonococcal infection at extragenital sites compared with culture in MSM, possibly because of lower bacterial loads at the pharynx and rectum.[61,62] Similar findings have been reported for chlamydia testing.[61] The prevalence of gonococcal and chlamydial infections varied by anatomical site in a study of MSM, which reported 53 percent of chlamydial and 64 percent of gonococcal infections occurring at rectal and pharyngeal sites, respectively.[63] In addition, 85 percent of rectal infections were asymptomatic and would only have been detected with routine screening. In another study of asymptomatic MSM, 84 percent of chlamydial and gonococcal infections were missed by testing for urethral infections only versus 9.8 percent of infections missed by screening only at the rectum and the pharynx.[60]

Future Research

Research is lacking on the effectiveness of screening for gonorrhea in all population groups and for chlamydia in men, pregnant women, and women without risk factors. Studies evaluating the effectiveness of different screening strategies for identifying persons at increased risk for infection, cotesting for concurrent STIs, and different screening intervals are needed to inform practice guidelines. For example, while no studies addressing repeat testing during pregnancy met inclusion criteria, an observational study conducted in the United States suggested that chlamydia test results in the first trimester may not predict chlamydia status during the third trimester.[56] Although studies of repeat testing have been conducted in some high-risk populations,[57] more research is warranted to further evaluate the value of repeat testing during pregnancy to reduce potential complications, such as preterm delivery and premature rupture of membranes.[58]

No studies provided data about potential adverse effects of screening other than those related to test performance for any of the asymptomatic population groups. An observational study of symptomatic and asymptomatic men and women who submitted self-collected specimens (from home) for chlamydia testing reported decreased anxiety after testing, although anxiety for women declined only after receiving negative results.[55] Waiting for test results generated anxiety and testing positive was associated with shock and distress for some participants, but many were glad that they had been tested. Additional studies on the harms of screening are needed.

Conclusions

Only one new trial of the effectiveness of screening for chlamydia in women,[26] one study of a risk prediction instrument,[29] and 10 studies of the diagnostic accuracy of screening tests met inclusion criteria. No studies addressed the effectiveness of screening for gonorrhea in all population groups and for chlamydia in men, pregnant women, and women without risk factors, or the effectiveness of different screening strategies. Aside from false-positive and false-negative findings, no studies provided data about other potential adverse effects of screening for any of the population groups. The findings of the POPI trial suggest benefits of screening for chlamydia for PID prevention, although results were not statistically significant. Screening with NAATs is accurate for diagnosing gonorrhea and chlamydia in asymptomatic persons regardless of specimen, anatomical site, or test. Further research is needed to understand the impact of screening for chlamydia and gonorrhea on clinical outcomes, effective screening strategies, and harms of screening.

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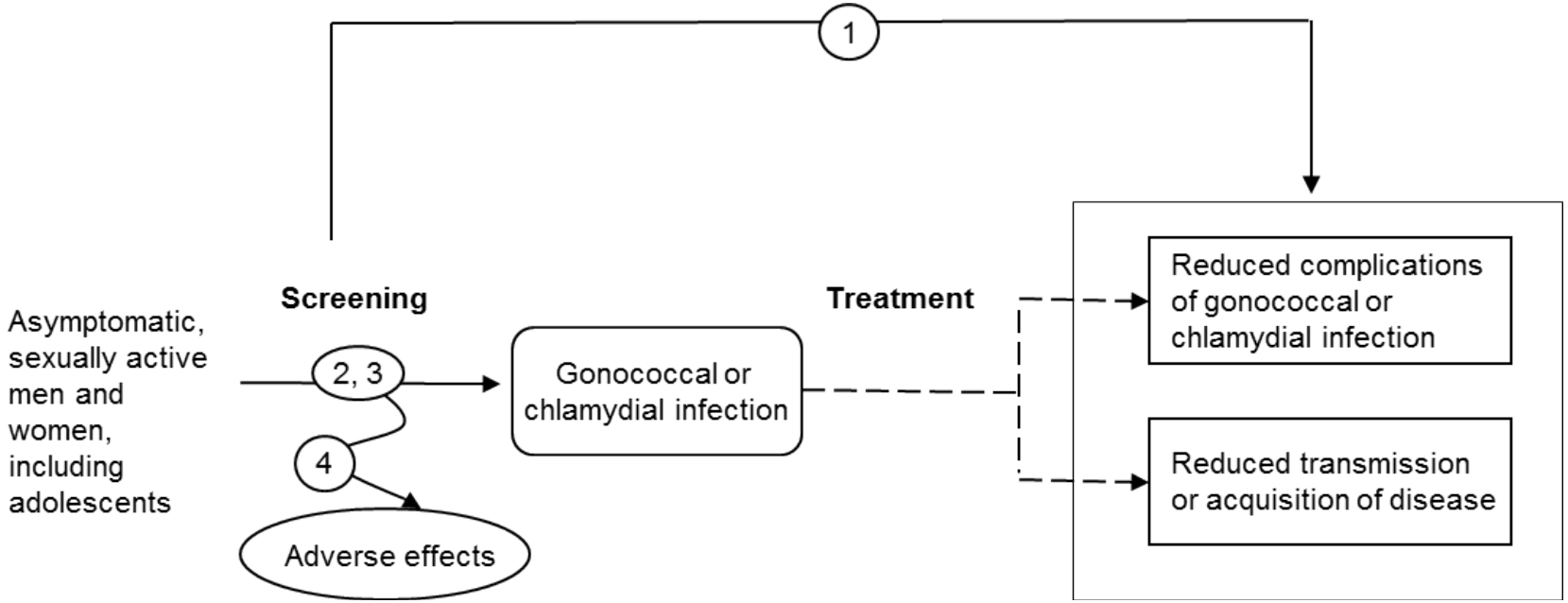
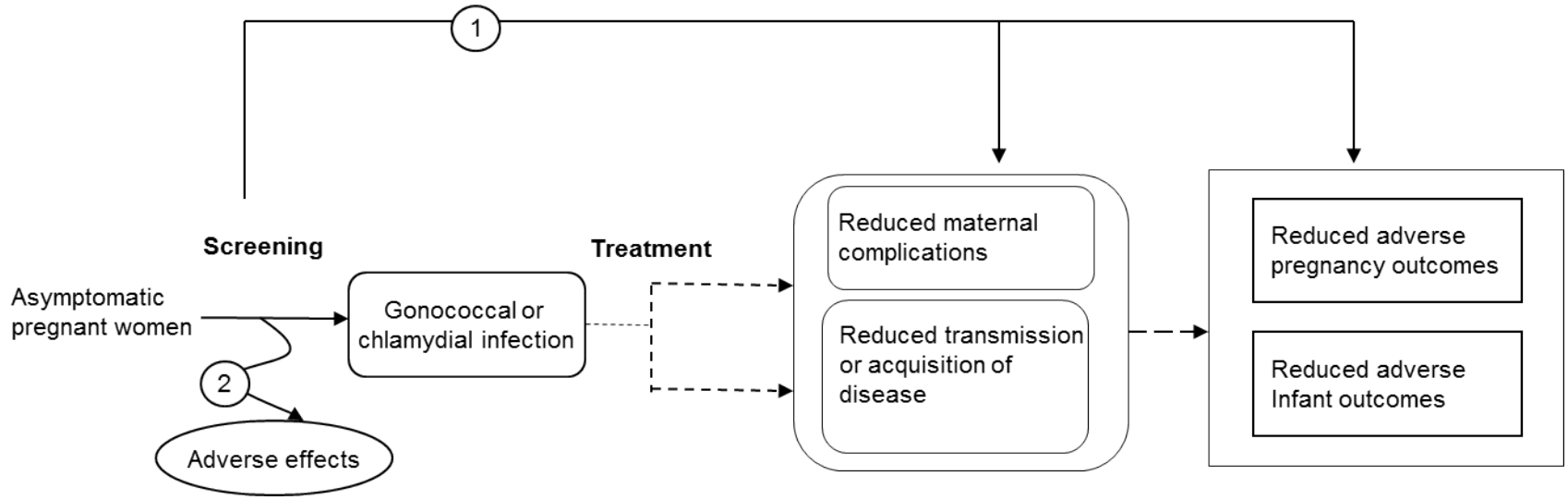
Figure 1. Analytic Framework: Screening in Men and Nonpregnant Women, Including Adolescents



Key Questions

1. How effective is screening for gonorrhea and chlamydia in reducing complications of infection and transmission or acquisition of disease in asymptomatic, sexually active men and nonpregnant women, including adolescents?
2. How effective are different screening strategies in identifying persons with gonorrhea and chlamydia?
3. How accurate are screening tests for detecting gonorrhea and chlamydia?
4. What are the harms of screening for gonorrhea and chlamydia?

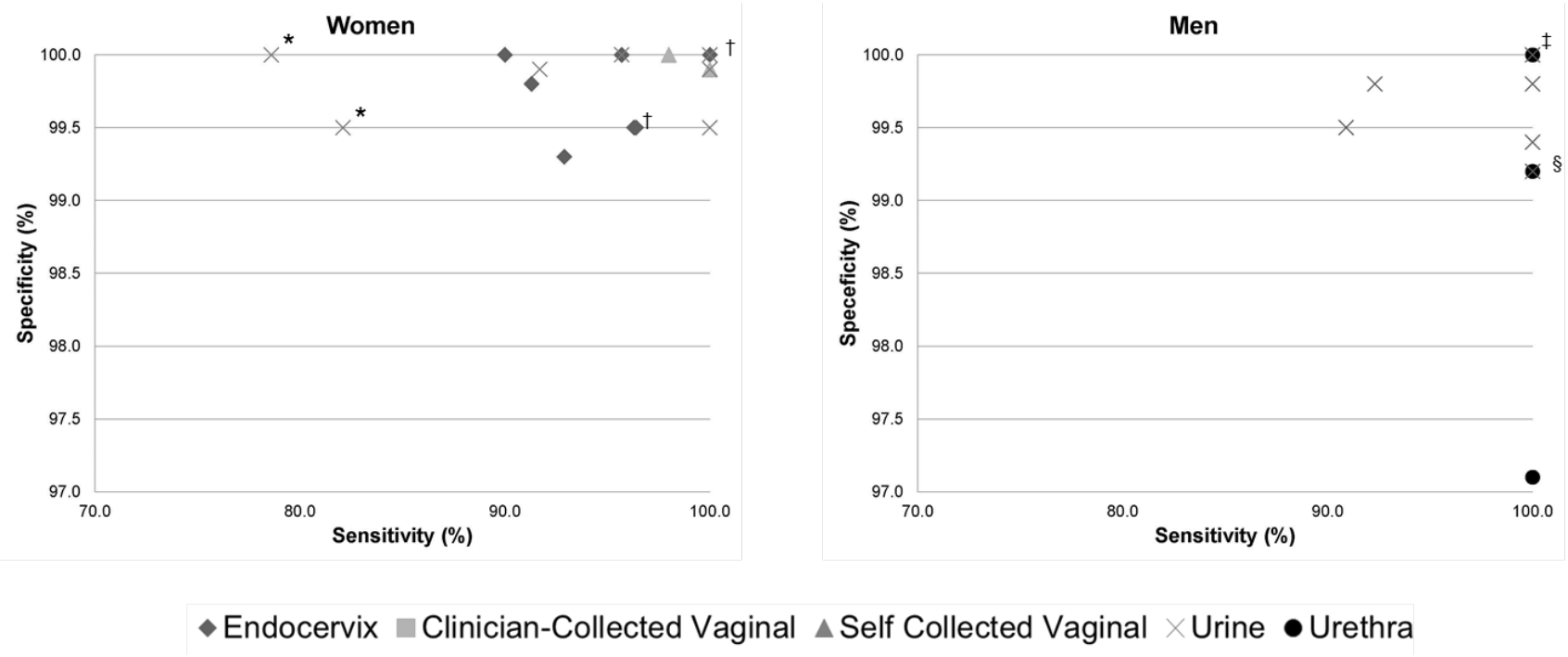
Figure 2. Analytic Framework: Screening in Pregnant Women



Key Questions

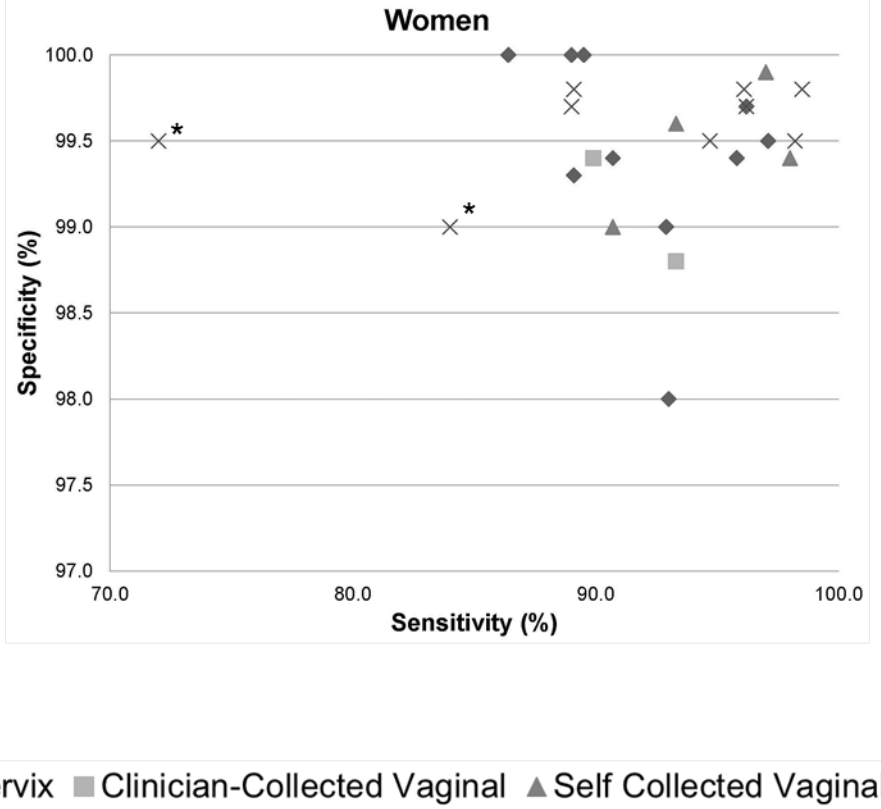
1. How effective is screening for gonorrhea and chlamydia in reducing maternal complications, adverse pregnancy and infant outcomes, and transmission or acquisition of disease in asymptomatic pregnant women?
2. What are the harms of screening for gonorrhea and chlamydia in asymptomatic pregnant women?

Figure 3. Diagnostic Accuracy of Nucleic Acid Amplification Tests for Screening for Gonorrhea in Men and Women



* The study reporting lower sensitivities for urine specimens in women (78.6% and 82.1%) used larger than recommended urine volumes,[34] differing from the other studies.
† Two studies produced identical data points for tests of the endocervix.
‡ Three data points for the urethra and three data points for urine.
§ Two data points for urethral samples.

Figure 4. Diagnostic Accuracy of Nucleic Acid Amplification Tests for Screening for Chlamydia in Women



*The study reporting lower sensitivities for urine specimens in women (72.0% and 84.0%) experienced technical and specimen processing errors,[37] differing from the other studies.

Figure 5. Diagnostic Accuracy of Nucleic Acid Amplification Tests for Screening for Chlamydia in Men

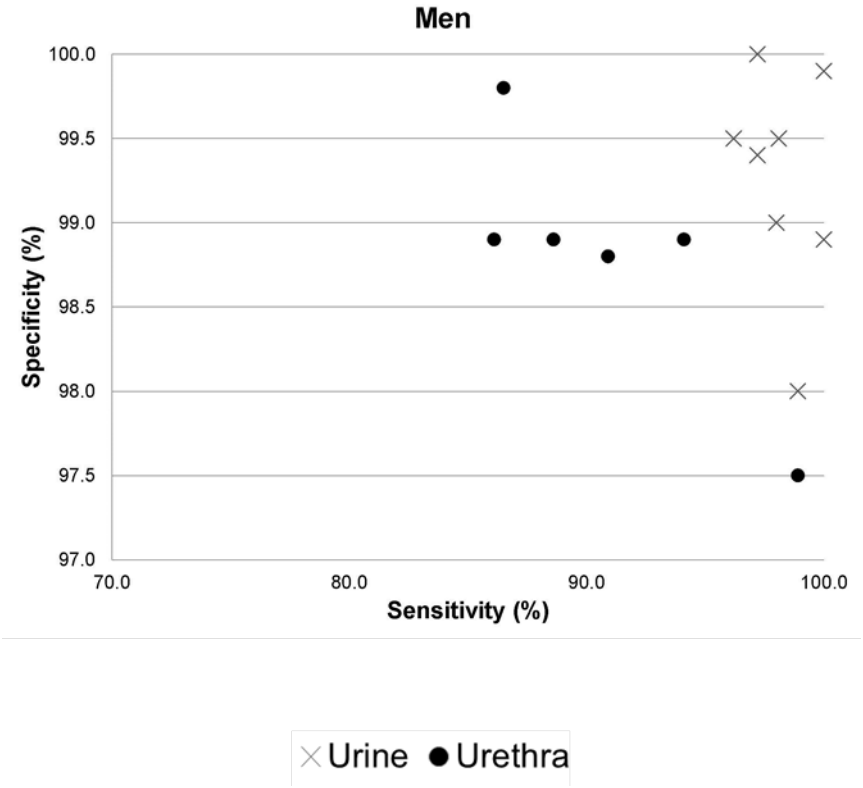


Table 1. Recommendations of Other Groups

Organization, year	Recommendations
Centers for Disease Control and Prevention (CDC), 2010[12]	The CDC recommendations are similar to those of the USPSTF for screening for gonorrhea in men and women. The CDC recommends annual screening for chlamydia in all sexually active women age ≤25 years and in older women with specific risk factors (e.g., a new or multiple sex partners) and screening for gonorrhea in sexually active women at increased risk for infection (e.g., those age <25 years). Because of high rates of reinfection, retesting for gonorrhea and chlamydia in infected persons is recommended 3 months after treatment. Routine screening for gonorrhea and chlamydia in the general population, including men, is not recommended. Clinical settings with a high prevalence of chlamydia should consider screening in sexually active young men. Also, adolescent and adult females age ≤35 years should be screened for gonorrhea and chlamydia at intake in juvenile detention or jail facilities. The CDC recommends screening annually for gonorrhea and chlamydia in men who have sex with men, based on exposure history, with more frequent screening recommended in highest-risk populations. High-risk pregnant women should be screened for gonorrhea and all pregnant women should be screened for chlamydia at their first prenatal visit. Pregnant women who continue to be at risk for these infections and those who test positive at their first prenatal visit should be retested in the third trimester.
American Congress of Obstetricians and Gynecologists (ACOG), 2010[42]	ACOG recommends annual screening for gonorrhea in high-risk females age <25 years. Annual screening for chlamydia is recommended in all sexually active females age ≤25 years. Adolescent and young adult males presenting to clinics associated with high chlamydia prevalence may be considered for screening.
American Medical Association, 2009[43]	Follow CDC recommendations.
American Academy of Pediatrics, 2011[44]	Follow CDC recommendations
American Academy of Family Physicians, 2007[45]	Follow USPSTF recommendations.
American College of Physicians, 2007[46]	Follow USPSTF recommendations.
Public Health Agency of Canada, 2010[64]	The Canadian guidelines recommend screening for gonorrhea and chlamydia in at-risk groups, including all sexually active males and females age <25 years, with repeat screening after 6 months in infected persons. Pregnant women should be screened for gonorrhea and chlamydia at the first prenatal visit and again during the third trimester for those who test positive or are high risk.

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

Author, Year	Population, *n*	Interventions	Duration	Attrition	Independent testing*	Outcomes	Quality
Oakeshott et al, 2010[26] (see text)	2,529 sexually active women age ≤27 years recruited from universities and colleges in the United Kingdom.	Immediate screening vs. deferred screening after 1 year (control)	1 year	Screened: 5% Control: 7%	Screened: 23% Control: 22%	Incidence of PID in asymptomatic women (n=1,648): Screened: 0.6% (5/787) Control: 1.6% (14/861) RR, 0.39 (95% CI, 0.14 to 1.08) Incidence of PID in all women: Screened: 1.3% (15/1191) Control: 1.9% (23/1186) RR, 0.65 (95% CI, 0.34 to 1.22)	Good
Prior reports							
Ostergaard et al, 2000[28]	1,700 female students recruited from high schools in one county in Denmark.	Home screening vs. usual care opportunistic screening in a clinic (control)	1 year	Screened: 49% Control: 42%	Screened: 29% Control: 36%	Incidence of new chlamydial infections in all females: Screened: 2.9% (13/443) Control: 6.6% (32/487) RR, 0.45 (95% CI, 0.24 to 0.84)† *p*=0.026 Incidence of PID in all females: Screened: 2.1% (9/443) Control: 4.2% (20/487) RR, 0.50 (95% CI, 0.23 to 1.08)† *p*=0.045	Poor‡
Scholes et al, 1996[27]	2,607 women ages 18 to 34 years recruited from a health maintenance organization in the United States, selected by risk criteria.	Clinic screening vs. usual care (control)	1 year	24% of participants did not return final questionnaire	Not reported	Incidence of PID in all women: Screened: 8 per 10,000 women-years (9 cases) Control: 18 per 10,000 women-years (33 cases) RR, 0.44 (95% CI, 0.20 to 0.90)	Good‡

*Only includes participants with followup who were independently tested outside of study protocol.
†Calculated.
‡As rated by prior review authors.

Abbreviations: CI = confidence interval; PID = pelvic inflammatory disease; RR = relative risk.

Table 3. Included Studies of Nucleic Acid Amplification Tests for Screening for Gonorrhea and Chlamydia At Various Anatomical Sites

Test	Anatomical site						
	Endocervix	Clinician-collected vagina	Self-collected vagina	Male urethra	Urine	Rectum	Pharynx
Gonorrhea							
GenProbe APTIMA COMBO 2	Van Der Pol et al, 2012[33] Van Der Pol et al, 2012[34] Stewart et al, 2012[35]	No studies	Stewart et al, 2012[46]	Taylor et al, 2012[32] Van Der Pol et al, 2012[34]	Taylor et al, 2012[32] Van Der Pol et al, 2012[33] Van Der Pol et al, 2012[34]	Not FDA approved site	Not FDA approved site
GenProbe APTIMA GC	No studies found	No studies	No studies	Chernesky et al, 2005[31]	Chernesky et al,2005[31]	Not FDA approved site	Not FDA approved site
BD ProbeTec ET	Van Der Pol et al, 2012[34]	No studies	No studies	Van Der Pol et al, 2012[34]	Van Der Pol et al, 2012[34]	Not FDA approved site	Not FDA approved site
BD ProbeTec CT/GC Q^X Amplified DNA Assay	Van Der Pol et al, 2012[33] Van Der Pol et al, 2012[34] Stewart et al, 2012[35]	No studies	No studies	Taylor et al, 2012[32] Van Der Pol et al, 2012[34]	Taylor et al, 2012[32] Van Der Pol et al, 2012[33] Van Der Pol et al, 2012[34]	Not FDA approved site	Not FDA approved site
Roche COBAS CT/NG test (c4800)	Van Der Pol et al, 2012[33] Van Der Pol et al, 2012[34] Stewart et al, 2012[35]	No studies	No studies	No studies	Taylor et al, 2012[32] Van Der Pol et al, 2012[33]	Not FDA approved site	Not FDA approved site
Cepheid GeneXpert CT/NG	Gaydos et al, 2013[36]	Not FDA approved site	Gaydos et al, 2013[36]	Not FDA approved site	Gaydos et al, 2013[36]	Not FDA approved site	Not FDA approved site
Chlamydia							
Roche COBAS AMPLICOR CT/NG Test	Schachter et al, 2003[37] Shrier et al, 2004[38]	Schachter et al, 2003[37] Shrier et al, 2004[38]	Schachter et al, 2003[37] Shrier et al, 2004[38]	No studies	Schachter et al, 2003[37] Shrier et al, 2004[38]	Not FDA approved site	Not FDA approved site
GenProbe APTIMA COMBO 2	Taylor et al, 2011[39] Van Der Pol et al, 2012[33] Schoeman et al, 2012[40]	No studies	Schoeman et al, 2012[40]	Taylor et al, 2012[32] Taylor et al, 2011[39]	Taylor et al, 2012[32] Taylor et al, 2011[39] Van Der Pol et al, 2012[33]	Not FDA approved site	Not FDA approved site
GenProbe APTIMA CT	Schachter et al, 2003[40]	Schachter et al, 2003[40]	Schachter et al, 2003[40]	Chernesky et al, 2005[31]	Schachter et al, 2003[37] Chernesky et al, 2005[31]	Not FDA approved site	Not FDA approved site
BD ProbeTec ET	Taylor et al, 2011[39]	No studies	No studies	Taylor et al, 2011[39]	Taylor et al, 2011[39]	Not FDA approved site	Not FDA approved site
BD ProbeTec CT/GC Q^X Amplified DNA Assay	Taylor et al, 2011[39] Van Der Pol et al, 2012[33]	No studies	No studies	Taylor et al, 2012[32]; Taylor et al, 2011[39]	Taylor et al, 2012[32] Taylor et al, 2011[39] Van Der Pol et al, 2012[33]	Not FDA approved site	Not FDA approved site
Roche COBAS CT/NG test (c4800)	Van Der Pol et al, 2012[33]	No studies	No studies	No studies	Taylor et al, 2012[32] Van Der Pol et al, 2012[33]	Not FDA approved site	Not FDA approved site

Table 3. Included Studies of Nucleic Acid Amplification Tests for Screening for Gonorrhea and Chlamydia At Various Anatomical Sites

Cepheid GeneXpert CT/NG	Gaydos et al, 2013[36]	Not FDA approved site	Gaydos et al, 2013[36]	Not FDA approved site	Gaydos et al, 2013[36]	Not FDA approved site	Not FDA approved site

Abbreviations: BD = Becton Dickinson; CT = *Chlamydia trachomatis*; ET = FDA = U.S. Food and Drug Administration; GC = gonorrhea/chlamydia; NG = *Neisseria gonorrhea*.

Table 4. Diagnostic Accuracy of Nucleic Acid Amplification Tests for Screening for Gonorrhea in Women

Test	Definition of a positive screening test	Reference standard	Prevalence (%)	TP (n)	FP (n)	FN (n)	TN (n)	Sens (%)	Spec (%)	PPV (%)	NPV (%)	PLR	NLR
Endocervix													
TMA[33]	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs	TMA SDA	1.5	23	0	0	2266	100.0	100.0	100.0*	100.0*	Unable to calculate	0.00*
TMA[34]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	6.5	27	2	1	418	96.4	99.5	93.1*	99.8*	202.5*	0.04*
PCR[33]	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs	TMA SDA	1.5	22	0	1	2246	95.7	100.0	100.0*,†	100.0*	Unable to calculate	0.04*
SDA[33]	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs	TMA SDA	1.5	21	4	2	2241	91.3	99.8	84.0*	99.9*	512.5*	0.09*
SDA[34]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	6.5	26	2	1	421	96.3	99.5	92.9*	99.8*	203.7*	0.04*
SDA[34]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	6.5	26	3	2	407	92.9	99.3	89.7*	99.5*	126.9*	0.07*
TMA[35]	Positive culture with biochemical confirmation or positive result from 1 NAAT confirmed by second NAAT	Culture TMA	2.5	36	0	4	2194	90.0	100.0	100.0*	98.8*	Unable to calculate	0.10*
PCR[36]	≥1 positive result from each reference NAAT	TMA SDA	1.1	12	0	0	1116	100.0	100.0	100.0	100.0	Unable to calculate	0.00*
Self-collected vaginal													
TMA[35]	Positive culture with biochemical confirmation or positive result from 1 NAAT confirmed by second NAAT	Culture TMA	2.5	39	0	1	2194	98.0	100.0*	100.0*	100.0*	Unable to calculate	0.03*
PCR[36]	≥1 positive result from each reference NAAT	TMA SDA	1.1	12	1	0	1119	100.0	99.9	92.3	100	1120.0*	0.00*
First-catch urine													
TMA[34]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	6.5	22	0	6	422	78.6	100.0	100.0*	98.6*	Unable to calculate	0.21*
TMA[33]	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs	TMA SDA	1.5	22	1	1	2268	95.7	100.0	95.7*	100.0*	2170.4*	0.04*

Table 4. Diagnostic Accuracy of Nucleic Acid Amplification Tests for Screening for Gonorrhea in Women

Test	Definition of a positive screening test	Reference standard	Prevalence (%)	TP (n)	FP (n)	FN (n)	TN (n)	Sens (%)	Spec (%)	PPV (%)	NPV (%)	PLR	NLR
PCR[33]	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs	TMA SDA	1.5	23	1	0	2255	100.0	100.0	95.8*	100.0*	2256.0*	0.00*
SDA[33]	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs	TMA SDA	1.5	23	3	0	2246	100.0	99.9	88.5*	100.0*	749.7*	0.00*
SDA[34]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	6.5	27	2	0	421	100.0	99.5	93.1*	100.0*	211.5*	0.00*
SDA[34]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	6.5	23	2	5	414	82.1	99.5	92.0*	98.8*	170.9*	0.18*
PCR[36]	≥1 positive result from each reference NAAT	TMA SDA	1.1	11	1	1	1123	91.7	99.9	91.7	99.9	1030.3*	0.08*

*Calculated.
†Estimated PPV, 93.8% to 99.9% (based on hypothetical prevalence range of 1% to 50%).

Abbreviations: FCU = first-catch urine; FN = false negative; FP = false positive; n = number; NAAT = nucleic acid amplification test; NG = *Neisseria gonorrhea*; NLR = negative likelihood ratio; NPV = negative predictive value; PCR = polymerase chain reaction; PLR = positive likelihood ratio; PPV = positive predictive value; SDA = strand displacement assay; Sens = sensitivity; Spec = specificity; TMA = transcription-mediated assay; TN = true negative; TP = true positive.

Table 5. Diagnostic Accuracy of Nucleic Acid Amplification Tests for Screening for Gonorrhea in Men

Test	Definition of a positive screening test	Reference standard	Prevalence (%)	TP (n)	FP (n)	FN (n)	TN (n)	Sens (%)	Spec (%)	PPV (%)	NPV (%)	PLR	NLR
Urethra													
TMA[31]	Both urethral swab and FCU positive on ≥1 of 2 NAATs; or positive on both tests for ≥1 specimen type	TMA SDA	13.8	110	21	0	710	100.0	97.1	84.0*	100.0*	34.8*	0.00*
TMA[32]	Positive result from ≥2 NAATs with different target regions in urethral swab and/or FCU	TMA SDA	9.2	7	0	0	465	100.0	100.0	100.0*	100.0*	Unable to calculate	0.00*
TMA[34]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	14.5	11	4	0	469	100.0	99.2	73.3*	100.0*	118.3*	0.00*
SDA[32]	Positive result from ≥2 NAATs with different target regions in urethral swab and/or FCU	TMA SDA	9.2	7	0	0	465	100.0	100.0	100.0*	100.0*	Unable to calculate	0.00*
SDA[34]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	14.5	12	4	0	492	100.0	99.2	75.0*	100.0*	124.0*	0.00*
SDA[34]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	14.5	12	0	0	480	100.0	100.0	100.0*	100.0*	Unable to calculate	0.00*
First-catch urine													
TMA[31]	Both urethral swab and FCU positive on ≥1 of 2 NAATs; or positive on both tests for ≥1 specimen type	TMA SDA	13.8	100	4	10	730	90.9	99.5	96.2*	98.7*	166.8*	0.09*
TMA[34]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	14.5	12	3	0	502	100.0	99.4	80.0*	100.0*	168.3*	0.00*
TMA[32]	Positive result from ≥2 NAATs with different target regions in urethral swab and/or FCU	TMA SDA	9.2	7	0	0	465	100.0	100.0	100.0*	100.0*	Unable to calculate	0.00*
PCR[32]	Positive result from ≥2 NAATs with different target regions in urethral swab and/or FCU	TMA SDA	9.2	7	0	0	465	100.0	100.0	100.0*	100.0*	Unable to calculate	0.00*
SDA[32]	Positive result from ≥2 NAATs with different target regions in urethral swab and/or FCU	TMA SDA	9.2	7	1	0	464	100.0	99.8	87.5*	100.0*	465.0*	0.00*
SDA[34]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	14.5	12	4	0	501	100.0	99.2	75.0*	100.0*	126.3*	0.00*
SDA[34]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	14.5	12	1	1	497	92.3	99.8	92.3*	99.8*	459.7*	0.08*
PCR[36]	≥1 positive result from each reference NAAT	TMA SDA	0.4	5	1	0	1126	100	99.9	83.3	100	1127.0*	0.00*

* Calculated.

Abbreviations: FCU = first-catch urine; FN = false negative; FP = false positive; n = number; NAAT = nucleic acid amplification test; NLR = negative likelihood ratio; NPV = negative predictive value; PCR = polymerase chain reaction; PLR = positive likelihood ratio; PPV = positive predictive value; SDA = strand displacement assay; Sens = sensitivity; Spec = specificity; TMA = transcription-mediated amplification; TN = true negative; TP = true positive.

Table 6. Diagnostic Accuracy of Nucleic Acid Amplification Tests for Screening for Gonorrhea and Chlamydia at Various Anatomical Sites

Test	Studies	Anatomical site									
		Endocervix		Clinician-collected vagina		Self-collected vagina		Male urethra		Urine	
		Sens (%)	Spec (%)	Sens (%)	Spec (%)	Sens (%)	Spec (%)	Sens (%)	Spec (%)	Sens (%)	Spec (%)
Gonorrhea											
GenProbe APTIMA COMBO 2	Van Der Pol et al, 2012[33]	100.0	100.0							F: 95.7	F: 100.0
	Van Der Pol et al, 2012[34]	96.4	99.5					100.0	99.2	F: 78.6 M: 100.0	F: 100.0 M: 99.4
	Stewart et al, 2012[35]	90.0	100.0			98.0	100.0				
	Taylor et al, 2012[32]							100.0	100.0	M: 100.0	M: 100.0
GenProbe APTIMA GC	Chernesky et al, 2005[31]							100	97.1	M: 90.9	M: 99.5
BD ProbeTec ET	Van Der Pol et al, 2012[34]	92.9	99.3					100.0	100.0	F: 82.1 M: 92.3	F: 99.5 M: 99.8
BD ProbeTec CT/GC Q^X Amplified DNA Assay	Van Der Pol et al, 2012[33]	91.3	99.8							F: 100.0	F: 99.9
	Van Der Pol et al, 2012[34]	96.3	99.5					100.0	99.2	F: 100.0 M: 100.0	F: 99.5 M: 99.2
	Taylor et al, 2012[32]							100.0	100.0	M: 100.0	M: 99.8
Roche COBAS CT/NG Test (c4800)	Van Der Pol et al, 2012[33]	95.7	100.0							F: 100.0	F: 100.0
	Taylor et al, 2012[32]									M: 100.0	M: 100.0
Cepheid GeneXpert CT/NG	Gaydos et al, 2013[36]	100.0	100.0			100.0	99.9			F: 91.7 M: 100.0	F: 99.9 M: 99.9
Chlamydia											
Roche COBAS AMPLICOR CT/NG Test	Schachter et al, 2003[37]	90.7	99.4	93.3	98.8	90.7	99.0			F: 84.0	F: 99.9
	Shrier et al, 2004[38]	51.9	100.0	55.6	100.0	51.9	99.0			F: 44.4	F: 100.0
GenProbe APTIMA COMBO 2	Schoeman et al, 2012[40]	89.0	100.0			97.0	99.9				
	Taylor et al, 2012[32]							94.1	98.9	M: 98.0	M: 99.0
	Taylor et al, 2011[39]	92.9	99.0					90.9	98.8	F: 98.2 M: 97.2	F: 99.5 M: 100.0
	Van Der Pol et al, 2012[33]	97.1	99.5							F: 92.5	F: 99.8
GenProbe APTIMA CT	Schachter et al, 2003[37]	89.1	99.3	89.9	99.4	93.3	99.6			F: 72.0	F: 99.5
	Chernesky et al, 2005[31]							98.9	97.5	M: 98.9	M: 98.0
BD ProbeTec ET	Taylor et al, 2011[39]	86.4	100.0					86.1	98.9	F: 89.8 M: 97.2	F: 99.7 M:99.4
BD ProbeTec CT/GC Q^X Amplified DNA Assay	Taylor et al, 2012[32]							86.5	99.8	M: 96.2	M: 99.5
	Taylor et al, 2011[39]	93.0	98.0					88.6	98.9	F: 94.7 M: 100.0	F: 99.5 M: 98.9
	Van Der Pol et al, 2012[33]	96.2	99.7							F: 96.2	F: 99.7
Roche COBAS CT/NG Test (c4800)	Taylor et al, 2012[32]									M: 98.1	M: 99.5
	Van Der Pol et al, 2012[33]	89.5	100.0							F: 89.1	F: 99.8
Cepheid GeneXpert CT/NG	Gaydos et al, 2013[36]	95.8	99.4			98.0	99.4			F: 96.1 M: 100.0	F: 99.8 M: 99.9

Abbreviations: BD = Becton Dickinson; CT = *Chlamydia trachomatis*; F = female; GC = gonorrhea/chlamydia; M = male; NG = *Neisseria gonorrhea*; Sens = sensitivity; Spec = specificity.

Table 7. Diagnostic Accuracy of Nucleic Acid Amplification Tests for Screening for Chlamydia in Women

Test	Definition of a positive screening test	Reference standard	Prevalence (%)	TP (n)	FP (n)	FN (n)	TN (n)	Sens (%)	Spec (%)	PPV (%)	NPV (%)	PLR	NLR
Endocervix													
TMA[37]	Agreement between positive results with vaginal swab and cervical swab or FCU	Culture	9.6	106*	10	13*	1262*	89.1	99.3	91.4*	99.0*	113.3*	0.11*
TMA[39]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	11.6	52	4	4	389	92.9	99.0	92.9*	99.0*	91.2*	0.07*
TMA[33]	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs	TMA SDA	6.3	101	12	3	2173	97.1	99.5	89.4*	99.9*	176.8*	0.03*
TMA[40]	Positive result from 1 NAAT confirmed by second NAAT	TMA	10.3	163	0	20	2050	89.0	100.0	100.0	99.0	Unable to calculate	0.11*
PCR[33]	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs	TMA SDA	6.3	94	1	11	2163	89.5	100.0	99.0*†	99.5*	1937.3*	0.10*
PCR[37]	Agreement between positive results with vaginal swab and cervical swab or FCU	Culture	9.6	68*	3	7*	503*	90.7	99.4	95.8*	98.6*	152.9*	0.09*
PCR[38]	1 positive culture or 2 positive nonculture tests, or 1 positive nonculture test confirmed by nested PCR	Culture PCR LCR	21.6	14	0	13	99	51.9	100.0	100.0	88.4	Unable to calculate	0.48*
SDA[33]	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs	TMA SDA	6.3	102	7	4	2155	96.2	99.7	93.6*	99.8*	297.2*	0.04*
SDA[39]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	11.6	53	8	4	385	93.0	98.0	86.9*	99.0*	45.7*	0.07*
SDA[39]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	11.6	51	0	8	379	86.4	100.0	100.0*	97.9*	Unable to calculate	0.14*
PCR[36]	≥1 positive result from each reference NAAT	TMA SDA	4.3	46	6	2	1074	95.8	99.4	88.5	99.8	172.5*	0.04*

Table 7. Diagnostic Accuracy of Nucleic Acid Amplification Tests for Screening for Chlamydia in Women

Test	Definition of a positive screening test	Reference standard	Prevalence (%)	TP (n)	FP (n)	FN (n)	TN (n)	Sens (%)	Spec (%)	PPV (%)	NPV (%)	PLR	NLR
First-catch urine													
TMA[37]	Agreement between positive results with vaginal swab and cervical swab or FCU	Culture	9.6	86*	7	33*	1265*	72.0	99.5	92.5*	97.5*	131.3*	0.28*
TMA[33]	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs	TMA SDA	6.3	98	5	8	2181	92.5	99.8	95.2*	99.6*	404.2*	0.08*
TMA[39]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	11.6	55	2	1	392	98.2	99.5	96.5*	99.8*	193.5*	0.02*
PCR[33]	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs	TMA SDA	6.3	98	4	12	2165	89.1	99.8	96.1*	99.5*	483.1*	0.11*
PCR[37]	Agreement between positive results with vaginal swab and cervical swab or FCU	Culture	9.6	63*	5	12*	501*	84.0	99.0	92.7*	97.7*	85.0*	0.16*
PCR[38]	1 positive culture or 2 positive nonculture tests, or 1 positive nonculture test confirmed by nested PCR	Culture PCR LCR	21.6	12	0	15	99	44.4	100.0	100.0	86.8	0.56*	Unable to calculate
SDA[33]	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs	TMA SDA	6.3	101	6	4	2161	96.2	99.7	94.4*	99.8*	347.4*	0.04*
SDA[39]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	11.6	54	2	3	391	94.7	99.5	96.4*	99.2*	186.2*	0.05*
SDA[39]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	11.6	53	1	6	384	89.8	99.7	98.2*	98.5*	345.9*	0.10*
PCR[36]	≥1 positive result from each reference NAAT	TMA SDA	4.5	49	2	2	1083	96.1	99.8	96.1	99.8	521.2*	0.04*
Clinician-collected vaginal													
TMA[37]	Agreement between positive results with vaginal swab and cervical swab or FCU	Culture	9.6	107*	9	12*	1263*	89.9	99.4	92.2*	99.1*	127.1*	0.10*

Table 7. Diagnostic Accuracy of Nucleic Acid Amplification Tests for Screening for Chlamydia in Women

Test	Definition of a positive screening test	Reference standard	Prevalence (%)	TP (n)	FP (n)	FN (n)	TN (n)	Sens (%)	Spec (%)	PPV (%)	NPV (%)	PLR	NLR
PCR[37]	Agreement between positive results with vaginal swab and cervical swab or FCU	Culture	9.6	70*	6	5*	500*	93.3	98.8	92.1*	99.0*	78.7*	0.07**
PCR[38]	1 positive culture or 2 positive nonculture tests, or 1 positive nonculture test confirmed by nested PCR	Culture PCR LCR	21.6	15	0	12	99	55.6	100.0	100.0*	89.2*	Unable to calculate	0.44*
Self-collected vaginal													
TMA[37]	Agreement between positive results with vaginal swab and cervical swab or FCU	Culture	9.6	111*	6	8*	1266*	93.3	99.6	94.9	99.4	197.8*	0.07*
PCR[37]	Agreement between positive results with vaginal swab and cervical swab or FCU	Culture	9.6	68*	5	7*	501*	90.7	99.0	93.2	98.6*	91.8*	0.09*
PCR[38]	1 positive culture or 2 positive nonculture tests, or 1 positive nonculture test confirmed by nested PCR	Culture PCR LCR	21.6	14	1	13	98	51.9	99.0	93.3	83.3	51.3*	0.49*
TMA[40]	Positive result from 1 NAAT confirmed by second NAAT	TMA	10.3	178	1	5	2049	97.0	99.9	99.4*	99.8*	1994.0*	0.03*
PCR[36]	≥1 positive result from each reference NAAT	TMA SDA	4.3	48	7	1	1076	98.0	99.4	87.3	99.9	151.6*	0.02*

*Calculated.
†Estimated PPV, 77.3% to 99.7% (based on hypothetical prevalence range of 1% to 50%).

Abbreviations: FCU = first-catch urine; FN = false negative; FP = false positive; LCR = ligase chain reaction; n = number; NAAT = nucleic acid amplification test; NLR = negative likelihood ratio; NPV = negative predictive value; PCR = polymerase chain reaction; PLR = positive likelihood ratio; PPV = positive predictive value; SDA = strand displacement assay; Sens = sensitivity; Spec = specificity; TMA = transcription-mediated amplification; TN = true negative; TP = true positive.

Table 8. Diagnostic Accuracy of Nucleic Acid Amplification Tests for Screening for Chlamydia in Men

Test	Definition of a positive screening test	Reference standard	Prevalence (%)	TP (n)	FP (n)	FN (n)	TN (n)	Sens (%)	Spec (%)	PPV (%)	NPV (%)	PLR	NLR
Urethra													
TMA[31]	Positive result from ≥1 NAAT in both urethral swab and FCU; or 1 specimen positive on both NAATs	TMA SDA	17.9	94	16	1	634	98.9	97.5	85.5*	99.8*	40.2*	0.01*
TMA[32]	Positive result from ≥2 NAATs with different target regions in urethral swab and/or FCU	TMA SDA	16.4	48	5	3	416	94.1	98.9	90.6*	99.3*	79.3*	0.06*
TMA[39]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	21.4	30	2	3	166	90.9	98.8	93.8*	98.2*	76.4*	0.09*
SDA[32]	Positive result from ≥2 NAATs with different target regions in urethral swab and/or FCU	TMA SDA	16.4	45	1	7	419	86.5	99.8	97.8*	98.4*	363.5*	0.13*
SDA[39]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	21.4	31	2	4	178	88.6	98.9	93.9*	97.8*	79.7*	0.12*
SDA[39]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	21.4	31	2	5	173	86.1	98.9	93.9*	97.2*	75.4*	0.14*
First-catch urine													
TMA[31]	Positive result from ≥1 NAAT in both urethral swab and FCU; or 1 specimen positive on both NAATs	TMA SDA	17.9	94	19	1	638	98.9	98.0†	83.2*	99.8*	34.2*	0.01*
TMA[32]	Positive result from ≥2 NAATs with different target regions in urethral swab and/or FCU	TMA SDA	16.4	50	4	1	417	98.0	99.0	92.6*	99.8*	103.2*	0.02*
TMA[39]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	21.4	35	0	1	179	97.2	100.0	100.0*	99.4*	Unable to calculate	0.03*
PCR[32]	Positive result from ≥2 NAATs with different target regions in urethral swab and/or FCU	TMA SDA	16.4	51	2	1	418	98.1	99.5	96.2*	99.8*	206.0*	0.02*
SDA[32]	Positive result from ≥2 NAATs with different target regions in urethral swab and/or FCU	TMA SDA	16.4	50	2	2	418	96.2	99.5	96.2*	99.5*	201.9*	0.04*
SDA[39]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	21.4	35	2	0	178	100.0	98.9	94.6*	100.0*	90.0*	0.00*

Table 8. Diagnostic Accuracy of Nucleic Acid Amplification Tests for Screening for Chlamydia in Men

Test	Definition of a positive screening test	Reference standard	Prevalence (%)	TP (n)	FP (n)	FN (n)	TN (n)	Sens (%)	Spec (%)	PPV (%)	NPV (%)	PLR	NLR
SDA[39]	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	TMA SDA	21.4	35	1	1	173	97.2	99.4	97.2*	99.4*	169.2*	0.03*
PCR[36]	≥1 positive result from each reference NAAT	TMA SDA	2.6	29	1	0	1102	100	99.9	96.7	100	1103.0*	0.00*

*Calculated.
†Study reported sensitivity noted above; calculated as 97.1%.

Abbreviations: FCU = first-catch urine; FN = false negative; FP = false positive; n = number; NAAT = nucleic acid amplification test; NLR = negative likelihood ratio; NPV = negative predictive value; PCR = polymerase chain reaction; PLR = positive likelihood ratio; PPV = positive predictive value; SDA = strand displacement assay; Sens = sensitivity; Spec = specificity; TMA = transcription-mediated amplification; TN = true negative; TP = true positive.

Table 9. Summary of Evidence

Main findings from prior USPSTF reviews	Number/type of studies in update	Overall quality*	Limitations	Consistency	Applicability	Summary of findings
Key Question 1. How effective is screening for gonorrhea and chlamydia in reducing complications of infection and transmission or acquisition of disease in asymptomatic, sexually active men and nonpregnant women, including adolescents?						
Chlamydia screening reduced PID in a good-quality RCT (RR, 0.44 [95% CI, 0.20 to 0.90]), but not in a poor-quality RCT (RR, 0.50 [95% CI, 0.23 to 1.08]).	1 good-quality RCT of chlamydia screening in women	Fair	Trial was potentially underpowered; 20% of women were tested outside of the trial. No studies of gonorrhea screening; no studies of chlamydia screening in other populations.	Point estimates consistent with prior trials, although statistical significance varies.	Study conducted in the United Kingdom using self-collected samples.	Screening a subset of asymptomatic young women for chlamydia did not statistically significantly reduce PID over the following year (RR, 0.39 [95% CI, 0.14 to 1.08]); one previous trial reported a reduction.
Key Question 2. How effective are different screening strategies in identifying persons with gonorrhea and chlamydia?						
Nine sets of selective screening criteria for chlamydial infection indicated that age alone had similar or better sensitivity and specificity than more extensive criteria.	1 observational study of chlamydia screening in women	Poor; studies are lacking	No studies of effectiveness, comparing cotesting for concurrent STIs, or evaluating different screening intervals.	NA	Study conducted in the Netherlands with limited applicability to the United States.	A risk prediction tool to identify persons with chlamydia in high-risk populations was not an accurate predictor and may not be relevant to U.S. practice. A previous study indicated that an age cut-off of ≤22 years would identify 80% of cases while testing 50% of women.
Key Question 3. How accurate are screening tests for detecting gonorrhea and chlamydia?						
25 studies of tests for gonorrhea and 33 for chlamydia indicated high accuracy, although studies included symptomatic persons and tests that are no longer used.	10 diagnostic accuracy studies of NAATs	Good	Unclear sampling methods, interpretation of tests, and inclusion of patients with uninterpretable results; some studies had technical shortcomings.	Consistent	Studies included high-prevalence populations (>5%).	Gonorrhea: sensitivity of 91% to 100% and specificity of ≥97% in studies without major limitations. Chlamydia: sensitivity of 86% to 100% and specificity of ≥97% in studies without major limitations. Previous findings are similar, but may not be clinically applicable.
Key Question 4. What are the harms of screening for gonorrhea and chlamydia?						
25 studies of tests for gonorrhea and 33 for chlamydia reported diagnostic accuracy. One qualitative interview study indicated anxiety with a positive test.	10 diagnostic accuracy studies of NAATs	Good for false-positive and false-negative rates; lack of other outcomes	No studies on other harms of screening, such as labeling or anxiety.	Consistent	Studies included high-prevalence populations (>5%).	Gonorrhea: false positive rate of ≤3%; false-negative rate of 0% to 9% in studies without major limitations. Chlamydia: false-positive rate of ≤3%; false-negative rate of 0% to 14% in studies without major limitations. Previous findings are similar, but may not be clinically applicable.
Key Question 1. How effective is screening for gonorrhea and chlamydia in reducing maternal complications, adverse pregnancy and infant outcomes, and transmission or acquisition of disease in asymptomatic pregnant women?						
No studies; prior reviews cited descriptive studies predating the searches.	No studies	NA	NA	NA	NA	NA

Table 9. Summary of Evidence

Main findings from prior USPSTF reviews	Number/type of studies in update	Overall quality*	Limitations	Consistency	Applicability	Summary of findings
Key Question 2. What are the harms of screening for gonorrhea and chlamydia in asymptomatic pregnant women?						
No studies met inclusion criteria.	No studies met inclusion criteria.	NA	NA	NA	NA	NA

*Overall quality is based on new evidence identified for the update plus previously reviewed evidence.

Abbreviations: CI = confidence interval; NA = not applicable; NAAT = nucleic acid amplification test; PID = pelvic inflammatory disease; RCT = randomized, control trial; RR = relative risk; STI = sexually transmitted infection.

Appendix A. Terminology

Area under receiver operating curve (AUC): Measure of how well a parameter can distinguish between two diagnostic groups.

Enzyme immunoassay (EIA): Assay designed to detect antigens of antibodies by producing an enzyme-triggered color change.

First-catch urine (FCU): Urine sample collected from individuals. Individuals should not have passed urine for at least 3 hours before sample collection. Individual collects first 10 mL of urine.

Indeterminate test result: Test result was not clear.

Negative likelihood ratio (NLR): Ratio between the probability of a negative test result given the presence of the disease and the probability of a negative test result given the absence of the disease.

Negative predictive value (NPV): Proportion of people with a negative test who are free of disease.

Nucleic acid amplification test (NAAT): Nucleic acid amplification tests detect small amounts of DNA or RNA in a test sample by using a series of repeated reactions to make multiple copies of the DNA or RNA that is being detected, thereby amplifying the signal from that piece of DNA or RNA. Several different categories exist, including:

- Transcription-mediated amplification (TMA)
- Strand displacement amplification (SDA)
- Polymerase chain reaction (PCR)
- Ligase chain reaction (LCR)

Number needed to invite (NNI): Average number of people who need to be invited to screen to find one positive case of disease/infection.

Number needed to screen (NNS): Average number of people who need to be screened to find one positive case of disease/infection.

Positive likelihood ratio (PLR): Ratio between the probability of a positive test result given the presence of the disease and the probability of a positive test result given the absence of the disease.

Positive predictive value (PPV): Proportion of people with a positive test who have the disease.

Relative risk (RR): Ratio of the risk of an event among an exposed population to the risk among the unexposed.

Sensitivity: Proportion of truly diseased/infected persons in the screened population who are identified as diseased by the screening test—that is, the true-positive rate.

Specificity: Proportion of truly nondiseased/noninfected persons who are identified as such by the screening test—that is, the true-negative rate.

Screening in Pregnant Women: Maternal and Neonatal Outcomes
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
---
1 exp GONORRHEA/
2 exp NEISSERIA GONORRHOEAE/
3 gonorrh$.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
4 1 or 2 or 3
5 exp mass screening/ or screen$.mp.
6 4 and 5
7 exp GONORRHEA/di
8 6 or 7
9 neonat$.mp. or exp Infant, Newborn/
10 8 and 9
11 maternal fetal transmission.mp. or exp Disease Transmission, Vertical/
12 exp GONORRHEA/tm [Transmission]
13 4 and 11
14 7 and 11
15 9 and 12
16 13 or 15
17 limit 16 to human
18 10 or 17

Risks
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
---
1 exp gonorrhea/
2 exp Neisseria gonorrhoeae/
3 1 or 2
4 exp Risk/
5 exp Risk Reduction Behavior/
6 exp Risk-Taking/
7 exp Risk Management/
8 4 or 5 or 6 or 7
9 3 or 8

Database: EBM Reviews – Cochrane Central Register of Controlled Trials
Search Strategy:
---
1 gonorrh$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
2 risk$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
3 1 and 2

Test Performance
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
---
1 exp gonorrhea/
2 exp Neisseria gonorrhoeae/
3 1 or 2
4 exp "Sensitivity and Specificity"/
5 exp Diagnostic Errors/
6 4 or 5
7 3 and 6

Database: EBM Reviews – Cochrane Central Register of Controlled Trials
Search Strategy:
---
1 gonorrh$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
2 (sensitiv$ or accurate$ or accuracy or predict$ or misdiagnos$ or misinterpret$ or ((diagnos$ or detect$ or discover$) adj5 (error$ or erroneous$ or fail$ or bias$)) or (false$ adj3 (positiv$ or negativ$))).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
3 1 and 2

Searches Conducted for Chlamydia Only

Overall
Database: EBM Reviews – Cochrane Central Register of Controlled Trials
Search Strategy:
---
1 chlamyd$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
2 risk$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
3 1 and 2
4 screen$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
5 1 and 4
6 (sensitiv$ or accurate$ or accuracy or predict$ or misdiagnos$ or misinterpret$ or ((diagnos$ or detect$ or discover$) adj5 (error$ or erroneous$ or fail$ or bias$)) or (false$ adj3 (positiv$ or negativ$))).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
7 1 and 6
8 3 or 5 or 7

Database: EBM Reviews – Cochrane Database of Systematic Reviews
Search Strategy:
---
1 chlamyd$.mp. [mp=title, abstract, full text, keywords, caption text]
2 risk$.mp. [mp=title, abstract, full text, keywords, caption text]
3 1 and 2
4 screen$.mp. [mp=title, abstract, full text, keywords, caption text]
5 1 and 4

6 (sensitiv$ or accurate$ or accuracy or predict$ or misdiagnos$ or misinterpret$ or ((diagnos$ or detect$ or discover$) adj5 (error$ or erroneous$ or fail$ or bias$)) or (false$ adj3 (positiv$ or negativ$))).mp. [mp=title, abstract, full text, keywords, caption text]
7 1 and 6
8 3 or 5 or 7

Database: EBM Reviews – Database of Abstracts of Reviews of Effects
Search Strategy:
---
1 chlamyd$.mp. [mp=title, full text, keywords]
2 (cost or costs or costing or fund or funding or funded or economic$ or expenditur$ or insuran$ or dollar$).mp. [mp=title, full text, keywords]
3 1 and 2
4 risk$.mp. [mp=title, full text, keywords]
5 1 and 4
6 screen$.mp. [mp=title, full text, keywords]
7 1 and 6
8 (sensitiv$ or accurate$ or accuracy or predict$ or misdiagnos$ or misinterpret$ or ((diagnos$ or detect$ or discover$) adj5 (error$ or erroneous$ or fail$ or bias$)) or (false$ adj3 (positiv$ or negativ$))).mp. [mp=title, full text, keywords]
9 1 and 8
10 3 or 5 or 7 or 9

Database: EBM Reviews – Health Technology Assessment
Search Strategy:
---
1 chlamyd$.mp. [mp=title, text, subject heading word]
2 risk$.mp. [mp=title, text, subject heading word]
3 1 and 2
4 screen$.mp. [mp=title, text, subject heading word]
5 1 and 4
6 (sensitiv$ or accurate$ or accuracy or predict$ or misdiagnos$ or misinterpret$ or ((diagnos$ or detect$ or discover$) adj5 (error$ or erroneous$ or fail$ or bias$)) or (false$ adj3 (positiv$ or negativ$))).mp. [mp=title, text, subject heading word]
7 1 and 6
8 3 or 5 or 7

Screening
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
---
1 exp chlamydia infections/
2 exp chlamydia trachomatis/
3 1 or 2
4 exp Mass Screening/
5 3 and 4

Database: EBM Reviews – Cochrane Central Register of Controlled Trials
Search Strategy:
---
1 chlamyd$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
2 screen$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
3 1 and 2

Screening in Pregnant Women – Maternal Outcomes
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
---
1 exp chlamydia infections/
2 exp chlamydia trachomatis/
3 1 or 2
4 exp mass screening/ or screen$.mp.
5 3 and 4
6 exp chlamydia infections/di
7 5 or 6
8 exp PREGNANCY/ or exp PREGNANCY COMPLICATIONS/
9 (septic$ adj3 abort$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
10 exp Fetal Death/
11 (stillborn or stillbirth$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
12 (preterm$ or prematur$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
13 exp Infant, Low Birth Weight/
14 (low adj3 birth weight$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
15 ((low or lower$ or reduc$) adj3 (weight$ or birthweight$)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
16 chorioamnionit$.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
17 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18 7 and 17

Screening in Pregnant Women – Neonatal Outcomes
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
---

1 exp chlamydia infections/
2 exp chlamydia trachomatis/
3 1 or 2
4 exp mass screening/ or screen$.mp.
5 3 and 4
6 exp chlamydia infections/di
7 5 or 6
8 neonat$.mp. or exp Infant, Newborn/
9 7 and 8
10 maternal fetal transmission.mp. or exp Disease Transmission, Vertical/
11 exp chlamydia infection/tm
12 7 and 10
13 8 and 11
14 12 or 13
15 limit 14 to human

Risks
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
---
1 exp chlamydia infections/
2 exp chlamydia trachomatis/
3 1 or 2
4 exp Risk/
5 exp Risk Reduction Behavior/
6 exp Risk-Taking/
7 exp Risk Management/
8 8 or 9 or 10 or 11
9 3 and 12

Database: EBM Reviews – Cochrane Central Register of Controlled Trials
Search Strategy:
---
1 chlamyd$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
2 risk$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
3 1 and 2

Test Performance
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
---
1 exp chlamydia infections/
2 exp chlamydia trachomatis/
3 1 or 2
4 exp "Sensitivity and Specificity"/
5 exp Diagnostic Errors/

6 4 or 5
7 3 and 6

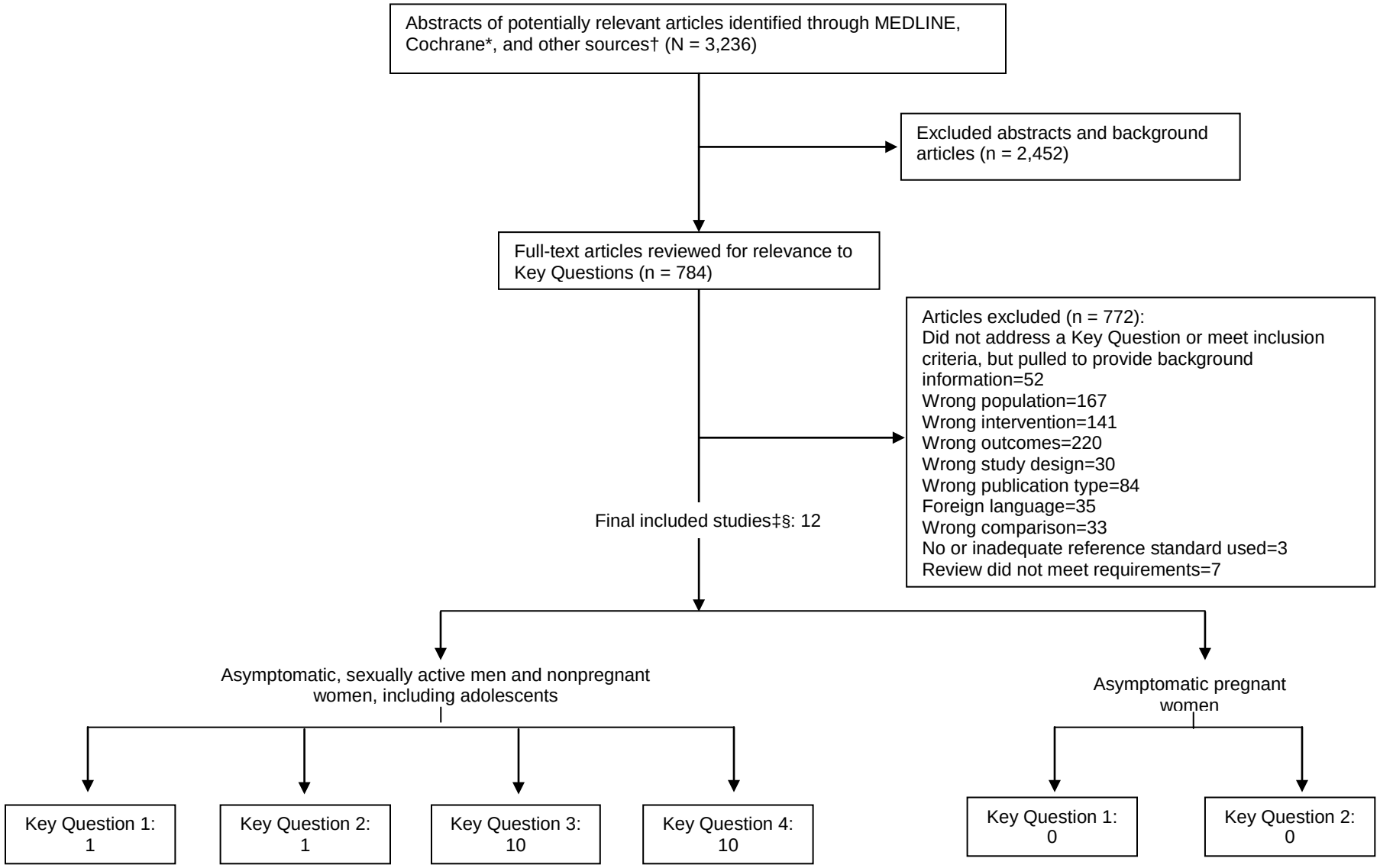
Database: EBM Reviews – Cochrane Central Register of Controlled Trials
Search Strategy:
---
1 chlamyd$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
2 (sensitiv$ or accurate$ or accuracy or predict$ or misdiagnos$ or misinterpret$ or ((diagnos$ or detect$ or discover$) adj5 (error$ or erroneous$ or fail$ or bias$)) or (false$ adj3 (positiv$ or negativ$))).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
3 1 and 2

Appendix B2. Inclusion and Exclusion Criteria

	Include	Exclude
Population	Asymptomatic, sexually active men and women (pregnant and nonpregnant), including adolescents	Symptomatic patients, children age <13 years, persons with other STIs
Interventions	Nonpregnant population: Screening effectiveness; screening strategies to detect infection, including selective screening of high-risk groups, sampling from various anatomical sites, cotesting for concurrent STIs, and use of different screening intervals; tests that detect chlamydia or gonorrhea in biological specimens from various anatomical sites (urine, endocervix, urethra, vagina, anus, pharynx) Pregnant population: Screening effectiveness	Tests that are not approved by the FDA
Outcomes	Nonpregnant population: Reduction in pelvic inflammatory disease, ectopic pregnancy, infertility, chronic pelvic pain, disease transmission, epididymitis, and other clinical outcomes; detection of infection and diagnostic accuracy; and harms from screening, such as labeling and false-negative or false-positive results Pregnant population: Reduction in disease transmission, preterm birth, neonatal clinical outcomes, and other pregnancy clinical outcomes	Intermediate outcomes
Study types and designs	All key questions: Good-quality systematic reviews Benefits: Randomized, control trials; controlled observational trials Harms: Randomized, control trials; controlled observational trials; and uncontrolled observational trials	Benefits: Uncontrolled observational trials, case studies Harms: Small uncontrolled observational trials, case studies

Abbreviations: FDA = U.S. Food and Drug Administration; STI = sexually transmitted infection.

Appendix B3. Literature Flow Diagram



*Cochrane databases include the Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews.
†Identified from reference lists, hand searching, and suggestions from experts.
‡Studies that provided data and contributed to the body of evidence were considered "included."
§Studies may have provided data for more than one Key Question.

Appendix B4. Excluded Studies

Key to exclusion codes

2	Excluded because it does not address a Key Question or meet inclusion criteria, but pulled to provide background information
3	Wrong population
4	Wrong intervention
5	Wrong outcomes
6	Wrong study design for Key Question
7	Wrong publication type
8	Foreign language
9	Appears in an included systematic review, no original data
10	Wrong comparison
11	No or inadequate reference standard used
12	Review did not meet our requirements

Molecular Diagnostics: LCR, the ligase chain reaction. 2003; http://chlamydiae.com/twiki/bin/view/Diagnostics/LcrTest. Accessed 22 May, 2013Exclusion code: 2.

Adderley-Kelly B, Stephens EM. Chlamydia: A major health threat to adolescents and young adults. *Abnf J.* 2005;16(3):52-55
Exclusion code: 6

Aghaizu A, Adams EJ, Turner K, et al. What is the cost of pelvic inflammatory disease and how much could be prevented by screening for chlamydia trachomatis? Cost analysis of the Prevention of Pelvic Infection (POPI) trial. *Sex Transm Infect.* 2011;87(4):312-317
Exclusion code: 5

Agrawal T, Vats V, Salhan S, Mittal A. Local markers for prediction of women at higher risk of developing sequelae to Chlamydia trachomatis infection. *Am J Reprod Immunol.* 2007;57(2):153-159
Exclusion code: 5

Akande V, Turner C, Horner P, Horne A, Pacey A, British Fertility S. Impact of Chlamydia trachomatis in the reproductive setting: British Fertility Society Guidelines for practice. *Hum Fertil (Camb).* 2010;13(3):115-125
Exclusion code: 6

Alary M, Poulin C, Bouchard C, et al. Evaluation of a modified sanitary napkin as a sample self-collection device for the detection of genital chlamydial infection in women. *J Clin Microbiol.* 2001;39(7):2508-2512
Exclusion code: 4

Aldeen T, Jacobs J, Powell R. Screening university students for genital chlamydial infection: another lesson to learn. *Sex Health.* 2010;7(4):491-494
Exclusion code: 5

Alexander S, Ison C. Evaluation of commercial kits for the identification of Neisseria gonorrhoeae. *J Med Microbiol.* 2005;54(Pt 9):827-831
Exclusion code: 10

Alexander S, Ison C, Parry J, et al. Self-taken pharyngeal and rectal swabs are appropriate for the detection of Chlamydia trachomatis and Neisseria gonorrhoeae in asymptomatic men who have sex with men. *Sex Transm Infect.* 2008;84(6):488-492
Exclusion code: 4

Alexander S, Martin I, Ison C. Confirming the Chlamydia trachomatis status of referred rectal specimens. *Sex Transm Infect.* 2007;83(4):327-329
Exclusion code: 5

Al-Tayyib AA, Miller WC, Rogers SM, et al. Evaluation of risk score algorithms for detection of chlamydial and gonococcal infections in an emergency department setting. *Acad Emerg Med.* 2008;15(2):126-135
Exclusion code: 10

Althaus CL, Heijne JCM, Roellin A, Low N. Transmission dynamics of Chlamydia trachomatis affect the impact of screening programmes. *Epidemics.* 2010;2(3):123-131
Exclusion code: 6

American Academy of Family Physicians. USPSTF Screening for Chlamydial Infection: Recommendation Statement. 2007; http://www.aafp.org/afp/2007/1201/p1695.html. Accessed 5 Dec, 2012
Exclusion code: 2.

Appendix B4. Excluded Studies

American Academy of Pediatrics. What's new with 2010 STD treatment guidelines from the CDC? 2011; http://aapnews.aappublications.org/content/32/2/7.full. Accessed 5 Dec, 2012
Exclusion code: 2.

American College of Obstetricians and Gynecologists. Committee opinion no. 506: expedited partner therapy in the management of gonorrhea and chlamydia by obstetrician-gynecologists. *Obstet Gynecol.* 2011;118(3):761-766
Exclusion code: 7

American College of Physicians. ACP Pocket Guide to Selected Preventive Services for Adults: Gonorrhea. 2012; http://www.acponline.org/mobile/cyppocketguide/gonorrhea_screening.html. Accessed 5 Dec, 2012
Exclusion code: 2.

American College of Physicians. ACP Pocket Guide to Selected Preventive Services for Adults: Chlamydia. 2012; http://www.acponline.org/mobile/cyppocketguide/chlamydia_screening.html. Accessed 5 Dec 2012
Exclusion code: 2.

American Medical Association, Moyer CS. STDs increasing among young women; more prevention urged. 2009; http://www.ama-assn.org/amednews/2009/12/07/prsb1207.htm. Accessed 5 Dec, 2012
Exclusion code: 2.

Amortegui AJ, Meyer MP. Enzyme immunoassay for detection of Chlamydia trachomatis from the cervix. *Obstet Gynecol.* 1985;65(4):523-526
Exclusion code: 4

Anagrius C, Mjornberg P-A. [Gathering round the Chlamydia infection problems: tests and contact tracing necessary--changed sexual behavior is also needed!]. *Lakartidningen.* 2006;103(28-29):2158; discussion 2160-2151
Exclusion code: 8

Andersen B, Gundgaard J, Kretzschmar M, Olsen J, Welte R, Oster-Gaard L. Prediction of costs, effectiveness, and disease control of a population-based program using home sampling for diagnosis of urogenital Chlamydia trachomatis Infections. *Sex Transm Dis.* 2006;33(7):407-415
Exclusion code: 3

Andersen B, Olesen F. Screening for Chlamydia trachomatis. *BMJ.* 2012;345:e4231
Exclusion code: 7

Andersen B, Olesen F, Moller JK, Ostergaard L. Population-based strategies for outreach screening of urogenital Chlamydia trachomatis infections: a randomized, controlled trial. *J Infect Dis.* 2002;185(2):252-258
Exclusion code: 3

Andersen B, Ostergaard L, Olesen F. [Lack of evidence to support chlamydia infection screening]. *Ugeskr Laeger.* 2010;172(28):2059-2061
Exclusion code: 7

Andersen B, Ostergaard L, Puho E, Skriver MV, Schonheyder HC. Ectopic pregnancies and reproductive capacity after Chlamydia trachomatis positive and negative test results: a historical follow-up study. *Sex Transm Dis.* 2005;32(6):377-381
Exclusion code: 4

Andersen B, Ostergaard L, Thomsen RW, Schonheyder H. Chlamydia trachomatis infection and risk of ectopic pregnancy. *Sex Transm Dis.* 2007;34(1):59; author reply 60
Exclusion code: 7

Andersen B, van Valkengoed I, Sokolowski I, Moller JK, Ostergaard L, Olesen F. Impact of intensified testing for urogenital Chlamydia trachomatis infections: a randomised study with 9-year follow-up. *Sex Transm Infect.* 2011;87(2):156-161
Exclusion code: 3

Anderson C, Thornley T. A pharmacy-based private chlamydia screening programme: results from the first 2 years of screening and treatment. *Int J Clin Pharm.* 2011;33(1):88-91
Exclusion code: 4

Andrews WW, Klebanoff MA, Thom EA, et al. Midpregnancy genitourinary tract infection with Chlamydia trachomatis: association with subsequent preterm delivery in women with bacterial vaginosis and Trichomonas vaginalis. *Am J Obstet Gynecol.* 2006;194(2):493-500
Exclusion code: 5

Angles d'Auriac M, Refseth UH, Espelund M, Moi H, Storvold G, Jeansson S. A new automated method for isolation of Chlamydia trachomatis from urine eliminates inhibition and increases robustness for NAAT systems. *J Microbiol Methods.* 2007;70(3):416-423
Exclusion code: 4

Appendix B4. Excluded Studies

Annan NT, Sullivan AK, Nori A, et al. Rectal chlamydia--a reservoir of undiagnosed infection in men who have sex with men. *Sex Transm Infect.* 2009;85(3):176-179
Exclusion code: 10

Anschuetz GL, Asbel L, Spain CV, et al. Association between enhanced screening for Chlamydia trachomatis and Neisseria gonorrhoeae and reductions in sequelae among women. *J Adolesc Health.* 2012;51(1):80-85
Exclusion code: 10

Anttila T, Tenkanen L, Lumme S, et al. Chlamydial antibodies and risk of prostate cancer. *Cancer Epidemiol Biomarkers Prev.* 2005;14(2):385-389
Exclusion code: 6

Arcari CM, Gaydos JC, Howell MR, McKee KT, Gaydos CA. Feasibility and short-term impact of linked education and urine screening interventions for Chlamydia and gonorrhea in male army recruits. *Sex Transm Dis.* 2004;31(7):443-447
Exclusion code: 4

Arustamian KK. [Risk factors of urogenital chlamydiosis in women of reproductive age]. *Georgian Med.* 2006(139):76-78
Exclusion code: 8

Arustamian KK. [Comparative analysis of methods for diagnostics of chlamydial infection in women of reproductive age]. *Georgian Med.* 2006(139):73-75
Exclusion code: 8

Arya R, Mannion PT, Woodcock K, Haddad NG. Incidence of genital Chlamydia trachomatis infection in the male partners attending an infertility clinic. *J Obstet Gynaecol.* 2005;25(4):364-366
Exclusion code: 2

Asbel LE, Newbern EC, Salmon M, Spain CV, Goldberg M. School-based screening for Chlamydia trachomatis and Neisseria gonorrhoeae among Philadelphia public high school students. *Sex Transm Dis.* 2006;33(10):614-620
Exclusion code: 10

Atherton H, Oakeshott P, Aghaizu A, Hay P, Kerry S. Use of an online questionnaire for follow-up of young female students recruited to a randomised controlled trial of chlamydia screening. *J Epidemiol Community Health.* 2010;64(7):580-584
Exclusion code: 4

Auerswald CL, Sugano E, Ellen JM, Klausner JD. Street-based STD testing and treatment of homeless youth are feasible, acceptable and effective. *J Adolesc Health.* 2006;38(3):208-212
Exclusion code: 10

Azariah S, McKernon S, Werder S. Large increase in opportunistic testing for chlamydia during a pilot project in a primary health organisation. *J Prim Health Care.* 2013;5(2):141-145
Exclusion code: 6

Bachmann LH, Johnson RE, Cheng H, et al. Nucleic acid amplification tests for diagnosis of Neisseria gonorrhoeae and Chlamydia trachomatis rectal infections. *J Clin Microbiol.* 2010;48(5):1827-1832
Exclusion code: 3

Bachmann LH, Johnson RE, Cheng H, Markowitz LE, Papp JR, Hook EW, 3rd. Nucleic acid amplification tests for diagnosis of Neisseria gonorrhoeae oropharyngeal infections. *J Clin Microbiol.* 2009;47(4):902-907
Exclusion code: 3

Bacon L. Chlamydia testing in contraceptive clinics: who, where, how and why? *J Fam Plann Reprod Health Care.* 2004;30(2):82-83
Exclusion code: 7

Baeten JM, Overbaugh J. Measuring the infectiousness of persons with HIV-1: opportunities for preventing sexual HIV-1 transmission. *Curr HIV Res.* 2003;1(1):69-86
Exclusion code: 2

Bakken IJ. Chlamydia trachomatis and ectopic pregnancy: recent epidemiological findings. *Curr Opin Infect Dis.* 2008;21(1):77-82
Exclusion code: 6

Bakken IJ, Bratt H, Skjeldestad FE, Nordbo SA. [Detection of chlamydia trachomatis in urine, vulval and cervical swabs]. *Tidsskr Nor Laegeforen.* 2005;125(12):1629-1630
Exclusion code: 8

Bakken IJ, Ghaderi S. Incidence of pelvic inflammatory disease in a large cohort of women tested for Chlamydia trachomatis: a historical follow-up study. *BMC Infect Dis.* 2009;9:130
Exclusion code: 6

Bakken IJ, Skjeldestad FE, Halvorsen TF, Thomassen T, Storvold G, Nordbo SA. Chlamydia trachomatis among young Norwegian men: sexual

behavior and genitourinary symptoms. *Sex Transm Dis.* 2007;34(4):245-249
Exclusion code: 6

Bakken IJ, Skjeldestad FE, Lydersen S, Nordbo SA. Births and ectopic pregnancies in a large cohort of women tested for Chlamydia trachomatis. *Sex Transm Dis.* 2007;34(10):739-743
Exclusion code: 3

Bakken IJ, Skjeldestad FE, Nordbo SA. Chlamydia trachomatis infections increase the risk for ectopic pregnancy: a population-based, nested case-control study. *Sex Transm Dis.* 2007;34(3):166-169
Exclusion code: 3

Bakken IJ, Skjeldestad FE, Ovreness T, Nordbo SA, Storvold G. [Chlamydia infections and sexual behavior among young women]. *Tidsskr Nor Laegeforen.* 2004;124(12):1633-1635
Exclusion code: 8

Baldwin SB, Djambazov B, Papenfuss M, et al. Chlamydial infection in women along the US-Mexico border. *Int J STD AIDS.* 2004;15(12):815-821
Exclusion code: 5

Balfe M, Brugha R, O'Connell E, Vaughan D, O'Donovan D. Men's attitudes towards chlamydia screening: a narrative review. *Sex Health.* 2012;9(2):120-130
Exclusion code: 5

Balla E. [Chlamydia trachomatis infections in neonates--overview of current laboratory diagnostics]. *Orv Hetil.* 2009;150(17):805-809
Exclusion code: 8

Bandea CI, Koumans EH, Sawyer MK, et al. Evaluation of the rapid BioStar optical immunoassay for detection of Chlamydia trachomatis in adolescent women. *J Clin Microbiol.* 2009;47(1):215-216
Exclusion code: 4

Bangor-Jones RD. Sexual health in general practice: do practitioners comply with the sexually transmitted infections guidelines for management of suspected chlamydial infections? *Int J STD AIDS.* 2011;22(9):523-524
Exclusion code: 3

Barabasi Z. [Treatment of conjunctivitis]. *Orv Hetil.* 2004;145(41):2107-2110
Exclusion code: 8

Baraitser P, Alexander S, Sheringham J. Chlamydia trachomatis screening in young women. *Curr Opin Obstet Gynecol.* 2011;23(5):315-320
Exclusion code: 7

Barbee L, Dombrowski JC, Kerani R, Golden MR. 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):168-172
Exclusion code: 4

Barry PM, Kent CK, Klausner JD. Risk factors for gonorrhea among heterosexuals--San Francisco, 2006. *Sex Transm Dis.* 2009;36(2 Suppl):S62-66
Exclusion code: 5

Barry PM, Kent CK, Philip SS, Klausner JD. Results of a program to test women for rectal chlamydia and gonorrhea. *Obstet Gynecol.* 2010;115(4):753-759
Exclusion code: 3

Barry PM, Kent CK, Scott KC, Goldenson J, Klausner JD. Is jail screening associated with a decrease in Chlamydia positivity among females seeking health services at community clinics?-San Francisco, 1997-2004. *Sex Transm Dis.* 2009;36(2 Suppl):S22-28
Exclusion code: 10

Barry PM, Kent CK, Scott KC, Snell A, Goldenson J, Klausner JD. Optimising sexually transmitted infection screening in correctional facilities: San Francisco, 2003-2005. *Sex Transm Infect.* 2007;83(5):416-418
Exclusion code: 10

Barry PM, Scott KC, McCright J, et al. Stay in school? Results of a sexually transmitted diseases screening program in San Francisco high schools-2007. *Sex Transm Dis.* 2008;35(6):550-552
Exclusion code: 10

Baseviciene I, Sumskas L. [Use of contraceptives among adolescent girls and its relation with the Chlamydia trachomatis infection]. *Medicina (Kaunas).* 2004;40(10):997-1003
Exclusion code: 5

Baud D, Regan L, Greub G. Comparison of five commercial serological tests for the detection of anti-Chlamydia trachomatis antibodies. *Eur J Clin Microbiol Infect Dis.* 2010;29(6):669-675
Exclusion code: 4

Appendix B4. Excluded Studies

Beebe JL, Masters H, Jungkind D, Heltzel DM, Weinberg A. Confirmation of the Syva MicroTrak enzyme immunoassay for chlamydia trachomatis by Syva Direct Fluorescent Antibody Test. *Sex Transm Dis.* 1996;23(6):465-470
Exclusion code: 3

Bekler C, Kultursay N, Ozacar T, Sayiner A, Yalaz M, Akisu M. Chlamydial infections in term and preterm neonates. *Jpn J Infect Dis.* 2012;65(1):1-6
Exclusion code: 3

Benn PD, Rooney G, Carder C, et al. Chlamydia trachomatis and Neisseria gonorrhoeae infection and the sexual behaviour of men who have sex with men. *Sex Transm Infect.* 2007;83(2):106-112
Exclusion code: 3

Benzaken AS, Galban EG, Antunes W, et al. Diagnosis of gonococcal infection in high risk women using a rapid test. *Sex Transm Infect.* 2006;82 Suppl 5:v26-28
Exclusion code: 4

Berger RE. Comparison of three nucleic acid amplification tests for detection of Chlamydia trachomatis in urine specimens. *J Urol.* 2005;173(6):1989-1990
Exclusion code: 7

Berger RE. Comparison of first void urine and urogenital swab specimens for detection of Mycoplasma genitalium and Chlamydia trachomatis by polymerase chain reaction in patients attending a sexually transmitted disease clinic. *J Urol.* 2005;173(6):1989-1990
Exclusion code: 7

Berman SM, Satterwhite CL. A paradox: overscreening of older women for Chlamydia while too few younger women are being tested. *Sex Transm Dis.* 2011;38(2):130-132
Exclusion code: 7

Bernstein KT, Marcus JL, Nieri G, Philip SS, Klausner JD. Rectal gonorrhea and chlamydia reinfection is associated with increased risk of HIV seroconversion. *J Acquir Immune Defic Syndr.* 2010;53(4):537-543
Exclusion code: 5

Bernstein KT, Marcus JL, Snell A, Liska S, Rauch L, Philip SS. Reduction in unnecessary Chlamydia screening among older women at title X-funded family planning sites following a structural intervention--San Francisco, 2009. *Sex Transm Dis.* 2011;38(2):127-129
Exclusion code: 6

Bernstein KT, Mehta SD, Rompalo AM, Erbelding EJ. Cost-effectiveness of screening strategies for Gonorrhea among females in private sector care. *Obstet Gynecol.* 2006;107(4):813-821
Exclusion code: 6

Berry SA, Ghanem KG, Page KR, et al. Increased gonorrhoea and chlamydia testing did not increase case detection in an HIV clinical cohort 1999-2007. *Sex Transm Infect.* 2011;87(6):469-475
Exclusion code: 3

Berwald N, Cheng S, Augenbraun M, Abu-Lawi K, Lucchesi M, Zehtabchi S. Self-administered vaginal swabs are a feasible alternative to physician-assisted cervical swabs for sexually transmitted infection screening in the emergency department. *Acad Emerg Med.* 2009;16(4):360-363
Exclusion code: 3

Bhalla P, Baveja UK, Chawla R, et al. Simultaneous detection of Neisseria gonorrhoeae and Chlamydia trachomatis by PCR in genitourinary specimens from men and women attending an STD clinic. *J Commun Dis.* 2007;39(1):1-6
Exclusion code: 3

Bialasiewicz S, Whiley DM, Buhrer-Skinner M, et al. A novel gel-based method for self-collection and ambient temperature postal transport of urine for PCR detection of Chlamydia trachomatis. *Sex Transm Infect.* 2009;85(2):102-105
Exclusion code: 4

Bielecki R, Zdrodowska-Stefanow B, Ostaszewska-Puchalska I, Kozlowski R, Pucilo K. [Role of Chlamydia trachomatis infection in the pathology of male urogenital tract]. *Przegl Lek.* 2004;61(3):170-176
Exclusion code: 8

Bignell C, Ison CA, Jungmann E. Gonorrhoea. *Sex Transm Infect.* 2006;82 Suppl 4:iv6-9
Exclusion code: 7

Bilardi JE, Sanci LA, Fairley CK, et al. The experience of providing young people attending general practice with an online risk assessment tool to assess their own sexual health risk. *BMC Infect Dis.* 2009;9:29
Exclusion code: 5

Appendix B4. Excluded Studies

Biro FM, Reising SF, Doughman JA, Kollar LM, Rosenthal SL. A comparison of diagnostic methods in adolescent girls with and without symptoms of Chlamydia urogenital infection. *Pediatrics.* 1994;93(3):476-480
Exclusion code: 4

Biros E, Bodnar J, Biros I, et al. Nucleic acid amplification technique for detection of Chlamydia trachomatis infection from clinical urogenital swabs. *Folia Microbiol (Praha).* 2007;52(4):437-442
Exclusion code: 4

Bissessor M, Tabrizi SN, Fairley CK, et al. Differing Neisseria gonorrhoeae bacterial loads in the pharynx and rectum in men who have sex with men: Implications for gonococcal detection, transmission, and control. *J Clin Microbiol.* 2011;49(12):4304-4306
Exclusion code: 2

Bjartling C, Persson K. [Chlamydia and genital mycoplasma: epidemiology and risks]. *Lakartidningen.* 2010;107(6):341-345
Exclusion code: 8

Blake DR. Approaches to Chlamydia screening: one size does not fit all. *Arch Pediatr Adolesc Med.* 2009;163(6):585-586
Exclusion code: 7

Blake DR, Lemay CA, Gaydos CA, Quinn TC. Performance of urine leukocyte esterase in asymptomatic male youth: another look with nucleic acid amplification testing as the gold standard for Chlamydia detection. *J Adolesc Health.* 2005;36(4):337-341
Exclusion code: 4

Blas MM, Canchihuaman FA, Alva IE, Hawes SE. Pregnancy outcomes in women infected with Chlamydia trachomatis: a population-based cohort study in Washington State. *Sex Transm Infect.* 2007;83(4):314-318
Exclusion code: 5

Blatt AJ, Lieberman JM, Hoover DR, Kaufman HW. Chlamydial and gonococcal testing during pregnancy in the United States. *Am J Obstet Gynecol.* 2012;207(1):55.e51-58
Exclusion code: 5

Bloom MS, Hu Z, Gaydos JC, Brundage JF, Tobler SK. Incidence rates of pelvic inflammatory disease diagnoses among Army and Navy recruits potential impacts of Chlamydia screening policies. *Am J Prev Med.* 2008;34(6):471-477
Exclusion code: 5

Boeke AJP, van Bergen JEAM, Morre SA, van Everdingen JJE. [The risk of pelvic inflammatory disease associated with urogenital infection with Chlamydia trachomatis; literature review]. *Ned Tijdschr Geneeskd.* 2005;149(16):878-884
Exclusion code: 8

Boel CHE, van Herk CMC, Berretty PJM, Onland GHW, van den Brule AJC. Evaluation of conventional and real-time PCR assays using two targets for confirmation of results of the COBAS AMPLICOR Chlamydia trachomatis/Neisseria gonorrhoeae test for detection of Neisseria gonorrhoeae in clinical samples. *J Clin Microbiol.* 2005;43(5):2231-2235
Exclusion code: 4

Bohm I, Groning A, Sommer B, Muller HW, Krawczak M, Glaubitz R. A German Chlamydia trachomatis screening program employing semi-automated real-time PCR: results and perspectives. *J Clin Virol.* 2009;46 Suppl 3:S27-32
Exclusion code: 5

Bone A, Soldan K, Woodhall S, Clarke J, Gill ON. Opportunistic or population register based programmes for chlamydia screening? *BMJ.* 2012;345:e5887
Exclusion code: 7

Bongaerts M, van de Bovenkamp JHB, Morre SA, Manders MELM, Heddema ER. Evaluation of the Siemens VERSANT[REGISTERED] CT/GC DNA 1.0 assay (kPCR) for detection of Chlamydia trachomatis and Neisseria gonorrhoeae. *J Microbiol Methods.* 2011;87(2):139-142
Exclusion code: 4

Borborema-Alfaia APBd, Freitas NSdL, Astolfi Filho S, Borborema-Santos CM. Chlamydia trachomatis infection in a sample of northern Brazilian pregnant women: prevalence and prenatal importance. *Braz J Infect Dis.* 2013;17(5):545-550
Exclusion code: 5

Borel N, Kempf E, Hotzel H, et al. Direct identification of chlamydiae from clinical samples using a DNA microarray assay: a validation study. *Mol Cell Probes.* 2008;22(1):55-64
Exclusion code: 3

Appendix B4. Excluded Studies

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Exclusion code: 5

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Exclusion code: 5

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Exclusion code: 5

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Exclusion code: 5

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Exclusion code: 5

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Exclusion code: 4

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Exclusion code: 4

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Exclusion code: 5

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Exclusion code: 7

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Exclusion code: 3

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Exclusion code: 3

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Exclusion code: 2

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Exclusion code: 3

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Exclusion code: 3

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Exclusion code: 4

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Exclusion code: 7

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Exclusion code: 5

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Exclusion code: 5

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Exclusion code: 5

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Mahony JB, Jang D, Chong S, et al. Detection of Chlamydia trachomatis, Neisseria gonorrhoeae, Ureaplasma urealyticum, and Mycoplasma genitalium in First-void Urine Specimens by Multiplex Polymerase Chain Reaction. *Mol Diagn.* 1997;2(3):161-168
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Exclusion code: 3

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Exclusion code: 5

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Exclusion code: 5

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Exclusion code: 5

Appendix B4. Excluded Studies

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Razali MF, Fairley CK, Hocking J, Bradshaw CS, Chen MY. Sampling technique and detection rates for pharyngeal gonorrhea using culture. *Sex Transm Dis.* 2010;37(8):522-524
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Exclusion code: 4

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Exclusion code: 2

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Exclusion code: 5

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Exclusion code: 4

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Exclusion code: 7

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Exclusion code: 7

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Exclusion code: 2

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Exclusion code: 5

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Exclusion code: 4

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Exclusion code: 3

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Exclusion code: 5

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Exclusion code: 3

van Dommelen L, Dukers-Muijrers N, van Tiel FH, Brouwers EEHG, Hoebe CJPA. Evaluation of one-sample testing of self-obtained vaginal swabs and first catch urine samples separately and in combination for the detection of Chlamydia trachomatis by two amplified DNA assays in women visiting a sexually transmitted disease clinic. *Sex Transm Dis.* 2011;38(6):533-535
Exclusion code: 3

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Exclusion code: 4

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Exclusion code: 5

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Exclusion code: 4

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Exclusion code: 3

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Exclusion code: 3

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Exclusion code: 3

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Exclusion code: 5

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Exclusion code: 4

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Exclusion code: 4

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Exclusion code: 4

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Exclusion code: 4

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Exclusion code: 5

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Exclusion code: 7

Walker J, Fairley CK, Walker SM, et al. Computer reminders for Chlamydia screening in general practice: a randomized controlled trial. *Sex Transm Dis.* 2010;37(7):445-450
Exclusion code: 4

Wallace LA, Scoular A, Hart G, Reid M, Wilson P, Goldberg DJ. What is the excess risk of infertility in women after genital chlamydia infection? A systematic review of the evidence. *Sex Transm Infect.* 2008;84(3):171-175
Exclusion code: 3

Wallin KL, Wiklund F, Luostarinen T, et al. A population-based prospective study of Chlamydia trachomatis infection and cervical carcinoma. *Int J Cancer.* 2002;101(4):371-374
Exclusion code: 2

Walsh A, Rourke FO, Crowley B. Molecular detection and confirmation of Neisseria gonorrhoeae in urogenital and extragenital specimens using the Abbott CT/NG RealTime assay and an in-house assay targeting the porA pseudogene. *Eur J Clin Microbiol Infect Dis.* 2011;30(4):561-567
Exclusion code: 3

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Exclusion code: 3

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Exclusion code: 5

Watchirs Smith LA, Hillman R, Ward J, et al. Point-of-care tests for the diagnosis of Neisseria gonorrhoeae infection: a systematic review of operational and performance characteristics. *Sex Transm Infect.* 2013;89(4):320-326
Exclusion code: 4

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Exclusion code: 12

Watson V, Ryan M, Watson E. Valuing experience factors in the provision of Chlamydia screening: an application to women attending the family planning clinic. *Value Health.* 2009;12(4):621-623

Exclusion code: 5

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Exclusion code: 5

Webley WC, Tilahun Y, Lay K, et al. Occurrence of Chlamydia trachomatis and Chlamydia pneumoniae in paediatric respiratory infections. *Eur Respir J.* 2009;33(2):360-367
Exclusion code: 5

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Exclusion code: 5

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Exclusion code: 5

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Exclusion code: 4

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Exclusion code: 3

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Exclusion code: 3

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Exclusion code: 3

Whiley DM, Goire N, Ray ES, et al. Neisseria gonorrhoeae multi-antigen sequence typing using non-cultured clinical specimens. *Sex Transm Infect.* 2010;86(1):51-55
Exclusion code: 3

Whiley DM, Sloots TP. Comparison of three in-house multiplex PCR assays for the detection of Neisseria gonorrhoeae and Chlamydia trachomatis using real-time and conventional detection methodologies. *Pathology.* 2005;37(5):364-370
Exclusion code: 4

Whiley DM, Tapsall JW, Sloots TP. Nucleic acid amplification testing for Neisseria gonorrhoeae: an ongoing challenge. *J Mol Diagn.* 2006;8(1):3-15
Exclusion code: 7

Wiehe SE, Rosenman MB, Wang J, Fortenberry JD. Disparities in chlamydia testing among young women with sexually transmitted infection symptoms. *Sex Transm Dis.* 2010;37(12):751-755
Exclusion code: 2

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Exclusion code: 5

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Exclusion code: 3

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Exclusion code: 5

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Exclusion code: 5

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Exclusion code: 3

Appendix B4. Excluded Studies

Winscott M, Taylor M, Kenney K. Sexually transmitted diseases among American Indians in Arizona: an important public health disparity. *Public Health Rep.* 2010;125 Suppl 4:51-60
Exclusion code: 5

Wong A, Maclean AB, Furrows SJ, Ridgway GL, Hardiman PJ, Perrett CW. Could epithelial ovarian cancer be associated with chlamydial infection? *Eur J Gynaecol Oncol.* 2007;28(2):117-120
Exclusion code: 5

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Exclusion code: 4

Workowski KA, Berman S. Sexually transmitted diseases treatment guidelines, 2010. *MMWR Recomm Rep.* 2010;59(12 RR):1-113
Exclusion code: 2

Wozniakowska-Gesicka T, Wisniewska-Ligier M, Kicinski P, Gesicki T. [Underestimated problem of Chlamydia infections]. *Przegl Epidemiol.* 2008;62 Suppl 1:133-141
Exclusion code: 8

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Exclusion code: 5

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Exclusion code: 4

Xiong L, Kong F, Zhou H, Gilbert GL. Use of PCR and reverse line blot hybridization assay for rapid simultaneous detection and serovar identification of Chlamydia trachomatis. *J Clin Microbiol.* 2006;44(4):1413-1418
Exclusion code: 4

Xu F, Stoner BP, Taylor SN, et al. Use of home-obtained vaginal swabs to facilitate rescreening for Chlamydia trachomatis infections: two randomized controlled trials. *Obstet Gynecol.* 2011;118(2 Pt 1):231-239
Exclusion code: 3

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Exclusion code: 3

Yang J-M, Liu H-X, Hao Y-X, He C, Zhao D-M. Development of a rapid real-time PCR assay for detection and quantification of four familiar species of Chlamydiaceae. *J Clin Virol.* 2006;36(1):79-81
Exclusion code: 4

Yeung A, Bush M, Cummings R, et al. Use of computerized medical records to determine the feasibility of testing for chlamydia without patients seeing a practitioner. *Int J STD AIDS.* 2010;21(11):755-757
Exclusion code: 4

Yip P-p, Chan W-h, Yip K-t, Que T-l, Kwong N-s, Ho C-k. The use of polymerase chain reaction assay versus conventional methods in detecting neonatal chlamydial conjunctivitis. *J Pediatr Ophthalmol Strabismus.* 2008;45(4):234-239
Exclusion code: 3

Young F. Sexually transmitted infections. Genital chlamydia: practical management in primary care. *J Fam Health Care.* 2005;15(1):19-21
Exclusion code: 7

Young H, Anderson J, Moyes A, McMillan A. Non-cultural detection of rectal and pharyngeal gonorrhoea by the Gen-Probe PACE 2 assay. *Genitourin Med.* 1997;73(1):59-62
Exclusion code: 2

Zampini AN. Emergency prevention: the benefit of chlamydia and gonorrhea screening in urban emergency departments. *J Emerg Nurs.* 2010;36(3):246-247
Exclusion code: 7

Zbroch T, Knapp P, Blonska E, Kobylec M, Knapp P. [Life style, Chlamydia trachomatis infection, bacterial vaginosis and their impact on the frequency of cervical lesions]. *Ginekol Pol.* 2004;75(7):538-544
Exclusion code: 8

Zenner D, Molinar D, Nichols T, Riha J, Macintosh M, Nardone A. Should young people be paid for getting tested? A national comparative study to evaluate patient financial incentives for chlamydia screening. *BMC Public Health.* 2012;12:261
Exclusion code: 5

Appendix B4. Excluded Studies

Zhang L-d, Pei J, Zhang H-m, Sun X-f. [Relationship between mycoplasma and chlamydia infection and lesions in the cervical tissue in high-risk HPV-positive patients]. *Chung Hua Shih Yen Ho Lin Chuang Ping Tu Hsueh.* 2010;24(5):346-348
Exclusion code: 8

Zheng H-p, Jiang L-f, Fang D-y, et al. Application of an oligonucleotide array assay for rapid detecting and genotyping of Chlamydia trachomatis from urogenital specimens. *Diagn Microbiol Infect Dis.* 2007;57(1):1-6
Exclusion code: 4

Zhong X-Y, Yu J-L, Wang J, et al. [Genotyping of major outer membrane protein gene of Chlamydia trachomatis by cleavase fragment length polymorphism analysis]. *Zhonghua Er Ke Za Zhi.* 2005;43(1):5-8
Exclusion code: 8

Zou H, Fairley CK, Guy R, Chen MY. The efficacy of clinic-based interventions aimed at increasing screening for bacterial sexually transmitted infections among men who have sex with men: a systematic review. *Sex Transm Dis.* 2012;39(5):382-387
Exclusion code: 4

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, crossovers, 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
- 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 at least 80%); reliable and valid measurement instruments are used and applied equally to the groups; interventions are spelled out clearly; important outcomes are considered; and appropriate attention to confounders in analysis. In addition, for RCTs, intention to treat analysis is used.

Fair: Studies will be 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 in follow-up; 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 done for RCTs.

Poor: Studies will be 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 at all equally among groups (including not masking outcome assessment); and key confounders are given little or no attention. For RCTs, intention to treat is lacking.

Diagnostic Accuracy Studies

Criteria:

- Screening test relevant, available for primary care, adequately described
- Study uses a credible reference standard, performed regardless of test results
- Reference standard interpreted independently of screening test
- Handles indeterminate results in a reasonable manner
- Spectrum of patients included in study
- Sample size
- Administration of reliable screening test

Definition of ratings based on above criteria:

Good: Evaluates relevant available screening test; uses a credible reference standard; interprets reference standard independently of screening test; reliability of test assessed; has few or handles indeterminate results in a reasonable manner; includes large number (more than 100) broad-spectrum patients with and without disease.

Fair: Evaluates relevant available screening test; uses reasonable although not best standard; interprets reference standard independent of screening test; moderate sample size (50 to 100 subjects) and a "medium" spectrum of patients.

Poor: Has fatal flaw such as: uses inappropriate reference standard; screening test improperly administered; biased ascertainment of reference standard; very small sample size of very narrow selected spectrum of patients.

Source: USPSTF Procedure Manual[24]

Appendix B6. Expert Reviewers

Heidi Bauer, MD, MS, MPH
Chief, Sexually Transmitted Disease, Control Branch, California Department of Public Health, CA; Adjunct Assistant Professor, Department of Epidemiology and Biostatistics, Division of Preventive Medicine and Public Health, University of California San Francisco, San Francisco, CA; Assistant Adjunct Professor, Division of Epidemiology, University of California Berkeley, Berkeley, CA

David D. Celentano, ScD, MHS
Professor, Charles Armstrong Chair, Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

Christopher Fairley, MBBS, PhD
Melbourne Sexual Health Centre, Alfred Hospital, Carlton, Victoria, Australia; Sexual Health Unit, Melbourne School of Population Health, The University of Melbourne, Carlton, Victoria, Australia

Khalil Ghanem, MD, PhD
Johns Hopkins University School of Medicine, Baltimore MD

Pippa Oakeshott, MA, MD
Division of Population Health Sciences, St. George's, University of London, United Kingdom

Stephanie N. Taylor, MD
Professor of Medicine and Microbiology, Section of Infectious Disease, Louisiania State University Health Sciences Center, New Orleans, LA; Clinic Administrator and Medical Director, Delgado Personal Health Center Sexually Transmitted Disease Clinic, New Orleans, LA

Rachel Gorwitz, MD, MPH
Medical Epidemiologist, Centers for Disease Control and Prevention

Sarah Kidd, MD, MPH
Medical Epidemiologist, Centers for Disease Control and Prevention

John Papp, PhD
Team Lead, Chlamydia and Gonorrhea Reference Laboratory, Centers for Disease Control and Prevention

Elizabeth Torrone, MSPH, PhD
Epidemiologist, Centers for Disease Control and Prevention

Appendix C1. Randomized, Controlled Trial of Effectiveness of Screening for Chlamydia

Author, year, title	Population characteristics	Eligibility criteria	Number approached, eligible, enrolled, & analyzed	Country & setting	Duration of followup	Attrition	Interventions	Outcomes	Adverse events/ harms	Sponsor	Quality rating
Oakeshott et al, 2010[26] (with data from personal communication) Prevention of Pelvic Infection (POPI) trial	Age (mean): 20.9 y 100% Female 61.1% White 27.2% Black 3.6% Asian 7.5% Other	Sexually active women age ≤27 y. Excluded those who have never had sexual intercourse, have been tested for chlamydial infection in the past 3 months, or were pregnant.	Approached: 3528 Eligible: 2563 Enrolled: 2529 Analyzed: 2377 (1648 asymptomatic women)	UK General population	1 y	Screened: 5% Deferred: 7%	Immediate screening vs. deferred screening after 1 y	Incidence of PID in asymptomatic women: Screened: 0.6% (5/787) Deferred: 1.6% (14/861) RR, 0.39 (95% CI, 0.14 to 1.08) In all women: Screened: 1.3% (15/1191) Deferred: 1.9% (23/1186) RR, 0.65 (95% CI, 0.34 to 1.22)	Not reported	Grant from the Bupa Foundation	Good

Abbreviations: CI = confidence interval; PID = pelvic inflammatory disease; RR = relative risk; UK = United Kingdom.

Appendix C2. Quality Rating of Randomized, Controlled Trial

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Attrition, crossovers, adherence, and contamination reported?	Loss to followup differential /high?	Patients analyzed in the groups to which they were randomized?	Post-randomization exclusions?	Outcomes pre-specified?	Funding source	External validity	Quality Rating
Oakeshott et al, 2010[26]	Yes	Yes	Yes	Yes	Yes	Screener: Yes Treatment: No	Yes	Yes	No/No	Yes	No	Yes	Grant from the Bupa Foundation	High	Good

Appendix C3. Observational Study of Screening Strategies for Chlamydia

Author, year, title	Study design	Country & setting	Interventions	Study duration Mean followup	Baseline demographics
Gotz et al, 2006[29] "Prediction of *Chlamydia trachomatis* infection: application of a scoring rule to other populations"	Observational Population-based setting	Amsterdam/ Rotterdam	Self-administered questionnaire to develop a prediction rule for probability of infection in participants A: CT pilot study, 2002 to 2003, n=6303 Validation study B: Amsterdam, 1996 to 1997, n=1788 C: Rotterdam, n=172 (high-risk youth)	1 year	**A, B, C** CT result Neg: 5997 (98%), 1361 (96%), 133 (88%) Pos: 144 (2%), 52 (4%), 19 (13%) Sex F: 4195 (68%), 913 (65%), 91 (60%) M: 1946 (32%), 500 (35%), 61 (40%) Age 15 to 19: 1386 (23%), 118 (8%), 87 (58%) 20 to 24: 2307 (38%), 440 (31%), 51 (34%) 25 to 29: 2448 (40%), 855 (61%), 12 (85%) Urogenital symptoms, women No: 4017 (96%), 870 (95%), 84 (92%) Yes: 178 (4%), 43 (5%), 7 (8%) Urogenital symptoms, men No: 1851 (95%), 480 (96%), 59 (97%) Yes: 95 (5%), 20 (4%), 2 (3%) Lifetime sexual partners 1: 2160 (35%), 248 (18%), 34 (22%) 2 to 5: 2904 (47%), 529 (37%), 66 (43%) ≥6: 1077 (18%), 636 (45%), 52 (34%)

Author, year, title	Eligibility criteria	Number enrolled Number analyzed Withdrawals Loss to followup	Adjusted variables for statistical analysis	Intermediate/clinical health outcome results	Adverse events/ harms	Sponsor	Quality rating
See above	Men and women ages 15 to 40 y; sexually active in the past 6 mo	Eligible: 21,000 Enrolled A: 6303 (41% participation rate) B: 1788 C: 172 Excluded: NR Analyzed A: 6141 B: 1413 C: 152 Withdrawals: NR Lost: NR	Discriminatory score AUC used as a model	Performance of predictor score at development and external validation: AUC* (95% CI) A: 0.79 (0.76 to 0.84) B: 0.66 (0.58 to 0.74) C: 0.68 (0.58 to 0.79) Predicted mean prevalence A: 2.3 B: 4.7 C: 8.9 Actual mean prevalence A: 2.3 B: 3.7 C: 12.5	NR	Rotterdam public health service	Good

* Results reflect higher homogeneity in risk factors.
Note: a model with an AUC of 0.5 has no discriminative power, whereas an AUC of 1 reflects perfect discrimination.

Abbreviations: AUC = area under curve; CI = confidence Interval; CT = *Chlamydia trachomatis*; F = female; M = male; n = number; Neg = negative; NNI = number needed to invite; NNS = number needed to screen; NR = not reported; Pos = positive.

Appendix C4. Quality Rating of Observational Study

Author, year	Did the study attempt to enroll all patients meeting inclusion criteria, or a random sample?	Were the groups comparable at baseline on key prognostic factors?	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 study maintain comparable groups?	Did the study perform appropriate statistical analyses on potential confounders?	Is there important differential or overall high loss to followup?	Were outcomes prespecified, defined, and ascertained using accurate methods?	Quality rating
Gotz et al, 2006[29]	Yes	Yes	Unclear	No	Yes	Yes	No	Yes	Good

Appendix C5. Diagnostic Accuracy Studies of Gonorrhea Tests

Study, year	Screening test	Definition of a positive screening exam	Reference standard	Country, Setting, Prevalence	Population characteristics
Chernesky et al, 2005[31]	AGC Site: urethral swab, FCU	Positive result from ≥1 NAAT in both urethral swab and FCU; or 1 specimen positive on both NAATs	AC2 PTGC	Canada, U.S. STI clinics	Age (mean): 28.5 y 100% male 62.2% non-Hispanic black, 24.6% white
Gaydos et al, 2013[36]	Xpert Site: self-collected vaginal, cervix, female FCU, male FCU	Positive result from at least 1 of the 2 reference NAATs	AC2 PTGC	U.S. STI clinics	Age: ≥14 y (range or mean NR) 45% male (full sample, asymptomatic information NR separately) Race: NR
Stewart et al, 2012[35]	AC2 Site: endocervical, self-collected vaginal	Positive culture with biochemical confirmation or positive result from 1 NAAT confirmed by second NAAT	Culture Aptima GC	United Kingdom Sexual health clinic Prevalence: NR	Age (mean): 25 y 100% female Ethnicity: 80% white, 9% black, 7% mixed, 4% other
Taylor et al, 2012[32]	c4800 Site: FCU AC2, CT/GC Q^X Site: FCU, urethral swab	Positive result from ≥2 NAATs with different target regions in urethral swab and/or FCU	AC2 CT/GC Q^X	U.S. Obstetrics/gynecology, family planning, and STI clinics Prevalence: ≥1%	Age: 55% ≤30 y 100% male Race: 64.7% black, 32.9% white, 0.4% Asian, 0.4% American Indian/Alaskan Native, 0.1% Hawaiian/Pacific Islander, 1.3% other, 0.1% unknown Ethnicity: 82.7% non-Hispanic, 15.1% Hispanic, 2.2% unknown
Van Der Pol et al, 2012[33]	c4800, AC2, CT/GC Q^X Site: endocervical, FCU	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATS	AC2 CT/GC Q^X	U.S. Family planning, obstetrics/gynecology, and STI clinics Prevalence NR	Age: ≥14 y 100% female Race: 43.1% black, 48.4% white, 2.8% Asian/Pacific Islander, 5.7% other Ethnicity: 22.1% Hispanic
Van Der Pol et al, 2012[34]	GCQ, PTNG, AC2 Site: endocervical, female FCU, urethral swab, male FCU,all female sites, all male sites, overall	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	AC2 PTNG	U.S. NG prevalence across sites (range): 1.4% to 19.2% in females; 4.8% to 40.5% in males	Age (range): 16 to 64 y 44% male Race: NR Note: 2.7% of females were pregnant

Study, year	Eligibility Criteria	Sample size Proportion with condition	Proportion unexaminable by screening test	Number of indeterminate results
Chernesky et al, 2005[31]	Men ages 15 to 77 y. Excluded if could not concurrently provide all samples, had urinated within 1 hour, had taken antibiotics in the last 21 days, or if they could not provide informed consent.	1322 enrolled 17.9% CT 13.8% NG	NR	NR
Gaydos et al, 2013[36]	Age ≥14 y, sexually active in the last 6 months, and attending a participating clinic. Excluded if enrolled in previous trial, received antimicrobial therapy within 21 days of study, or history of hysterectomy.	2,270 asymptomatic 3.5% CT 0.7% NG	NR	0.25% (total sample) were invalid and unreadable
Stewart et al, 2012[35]	Women age ≥16 y presenting to study clinic for a new visit. Excluded if used antibiotics in the last 28 days, were unable or unwilling to perform self-taken swab or have the standard examination and swabs performed by clinicians.	3973 enrolled 2.5% with NG	0.8%	None
Taylor et al, 2012[32]	Men age ≥14 y. Excluded if they had been previously enrolled in the study or used antimicrobials effective against CT or NG in the last 21 days.	768 enrolled 16.4% CT 9.2% NG	2.9%	NR
Van Der Pol et al, 2012[33]	Women age ≥14 y who were eligible for routine CT/NG screening as per standard practice at each enrollment site. Excluded if they had been previously enrolled, used antimicrobial agents active against CT or NG in last 21 days, used Raplense (a vaginal lubricant) within past 3 days, or had a	4479 enrolled 6.3% CT 1.5% NG	3.6% of enrolled; 16.4% for primary analysis of particular specimen type	NR

Appendix C5. Diagnostic Accuracy Studies of Gonorrhea Tests

Study, year	Eligibility Criteria	Sample size Proportion with condition	Proportion unexaminable by screening test	Number of indeterminate results
	history of hysterectomy or contraindication to Pap test/cervical sampling.			
Van Der Pol et al, 2012[34]	Men and women ages 16 to 64 y who presented with urogenital symptoms or were being screened for CT and NG. Excluded if they had urinated within 1 hour of specimen collection, used antibiotics within last 21 days, had prior study enrollment, failed to provide consent, or were younger than the age required by the sites' IRB.	1846 enrolled 6.5% of females with NG 14.5% of males with NG	4.2% 12% of males had only 2 urethral swabs collected, rather than 3	21 indeterminate from PTNG; 9/21 resolved negative with repeat testing, 12 remained indeterminate. All were negative by GCQ and AC2.

Study, year	Screening test	Proportion with reference standard & included in analysis	True positives	False positives	False negatives	True negatives	Sensitivity (95% CI)	Specificity (95% CI)
Chernesky et al, 2005[31]	AGC Site: urethral swab	100%	110	21	0	710	100.0% (71.5 to 100) Calculated CI: 96.7 to 100	97.1% (95.6 to 98.2)
	AGC Site: FCU		100	4	10	730	90.9% (58.7 to 99.8) Calculated CI: 83.9 to 95.6	99.5% (98.6 to 99.9)
Gaydos et al, 2013[36]	Xpert Site: self-collected vaginal	99.6%	12	1	0	1119	100% (77.9 to 100)	99.9% (99.5 to 100)
	Xpert Site: cervix		12	0	0	1116	100% (77.9 to 100)	100% (99.7 to 100)
	Xpert Site: female FCU		11	1	1	1123	91.7% (61.5 to 99.8)	99.9% (99.5 to 100)
	Xpert Site: male FCU		5	1	0	1126	100% (54.9 to 100)	99.9% (99.5 to 100)
Stewart et al, 2012[35]	AC2 Site: endocervical	97%	36	0	4	2194	90.0% (77.0 to 96.0)	100.0% (99.8 to 100.0)*
	AC2 Site: self-collected vaginal		39	0	1	2194	98.0% (87.0 to 100.0)	100.0% (99.8 to 100.0)*
Taylor et al, 2012[32]	c4800 Site: FCU	97.1%	7	0	0	465	100.0% (64.6 to 100.0) Calculated CI: 58.9 to 100	100.0% (99.2 to 100.0)
	AC2 Site: FCU		7	0	0	465	100.0% (64.6 to 100.0) Calculated CI: 58.9 to 100	100.0% (99.2 to 100.0)
	AC2 Site: urethral swab		7	0	0	465	100.0% (64.6 to 100.0) Calculated CI: 58.9 to 100	100.0% (99.2 to 100.0)
	CT/GC Q^X Site: FCU		7	1	0	464	100.0% (64.6 to 100.0) Calculated CI: 58.9 to 100	99.8% (98.8 to 100.0)
	CT/GC Q^X Site: urethral swab		7	0	0	465	100.0% (64.6 to 100.0) Calculated CI: 58.9 to 100	100.0% (99.2 to 100.0)
Van Der Pol et al, 2012[33]	c4800 Site: endocervical	96.4%	22	0	1	2246	95.7% (79.0 to 99.2)	100.0% (99.8 to 100.0)
	c4800 Site: FCU		23	1	0	2255	100.0% (85.7 to 100.0)	100.0% (99.7 to 100.0)
	AC2 Site: endocervical		23	0	0	2266	100.0% (85.7 to 100.0)	100.0% (99.8 to 100.0)
	AC2 Site: FCU		22	1	1	2268	95.7% (79.0 to 99.2)	100.0% (99.8 to 100.0)
	CT/GC Q^X Site: endocervical		21	4	2	2241	91.3% (73.2 to 97.6)	99.8% (99.5 to 99.9)
	CT/GC Q^X Site: FCU		23	3	0	2246	100.0% (85.7 to 100.0)	99.9% (99.6 to 100.0)

Appendix C5. Diagnostic Accuracy Studies of Gonorrhea Tests

Study, year	Screening test	Proportion with reference standard & included in analysis	True positives	False positives	False negatives	True negatives	Sensitivity (95% CI)	Specificity (95% CI)
Van Der Pol et al, 2012[34]	GCQ Site: endocervical	95.8%	26	2	1	421	96.3% (81.0 to 99.9)	99.5% (98.3 to 99.9)
	GCQ Site: female FCU		27	2	0	421	100.0% (87.2 to 100.0)	99.5% (98.3 to 99.9)
	GCQ Site: urethral swab		12	4	0	492	100.0% (73.5 to 100.0)	99.2% (97.9 to 99.8)
	GCQ Site: male FCU		12	4	0	501	100.0% (73.5 to 100.0%)	99.2% (98.0 to 99.8%)
	GCQ All female sites		106	13	2	1678	98.1% (93.5 to 99.8)	99.2% (98.7 to 99.6)
	GCQ All male sites		36	12	0	1494	100.0% (90.3 to 100.0)	99.2% (98.6 to 99.6)
	GCQ Overall		142	25	2	3172	98.6% (95.1 to 99.8)	99.2% (98.8 to 99.5)
	PTNG Site: endocervical		26	3	2	407	92.9% (76.5 to 99.1)	99.3% (97.9 to 99.8)
	PTNG Site: female FCU		23	2	5	414	82.1% (63.1 to 93.9)	99.5% (98.3 to 99.9)
	PTNG Site: urethral swab		12	0	0	480	100.0% (73.5 to 100.0)	100.0% (99.2 to 100.0)
	PTNG Site: male FCU		12	1	1	497	92.3% (64.0 to 99.8)	99.8% (98.9 to 100.0)
	PTNG All female sites		49	5	7	821	87.5% (75.9 to 94.8)	99.4% (98.6 to 99.8)
	PTNG All male sites		24	1	1	977	96.0% (79.6 to 99.9)	99.9% (99.4 to 100.0)
	PTNG Overall		73	6	8	1798	90.1% (81.5 to 95.6)	99.7% (99.3 to 99.9)
	AC2 Site: endocervical		27	2	1	418	96.4% (81.7 to 99.9)	99.5% (98.3 to 99.9)
	AC2 Site: female FCU		22	0	6	422	78.6% (59.0 to 91.7)	100.0% (99.1 to 100.0)
	AC2 Site: urethral swab		11	4	0	469	100.0% (71.5 to 100.0)	99.2% (97.8 to 99.8)
	AC2 Site: male FCU		12	3	0	502	100.0% (73.5 to 100.0)	99.4% (98.3 to 99.9)
	AC2 All female sites		49	2	7	840	87.5% (75.9 to 94.8)	99.8% (99.1 to 100.0)
	AC2 All male sites		23	7	0	971	100.0% (85.2 to 100.0)	99.3% (98.5 to 99.7)
	AC2 Overall		72	9	7	1811	91.1% (82.6 to 96.4)	99.5% (99.1 to 99.8)

Study, year	Screening test	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)	Sponsor	Quality rating
Chernesky et al, 2005[31]	AGC Site: urethral swab	34.8 (22.8 to 53.1)*	0.00*	84.0% (76.5 to 89.8)*	100% (99.5 to 100.0)*	NR	Fair
	AGC Site: FCU	166.8 (62.7 to 444.1)*	0.09 (0.05 to 0.17)*	96.2% (90.4 to 98.9)*	98.7% (97.5 to 99.4)*		

Appendix C5. Diagnostic Accuracy Studies of Gonorrhea Tests

Study, year	Screening test	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)	Sponsor	Quality rating
Gaydos et al, 2013[36]	Xpert Site: self-collected vaginal	1120.0 (157.90 to 7944.29)*	0.00*	92.3% (63.9 to 98.7)	100% (99.7 to 100)	Cepheid, grant from National Insitute of Biomedical Imaging and Bioengineering	Fair
	Xpert Site: cervix	Unable to calculate	0.00*	100.0% (73.4 to 100)	100.0% (99.7 to 100)		
	Xpert Site: female FCU	1030.3 (144.2 to 7362.7)*	0.08 (0.01 to 0.54)*	91.7% (61.5 to 98.6)	99.9% (99.5 to 99.9)		
	Xpert Site: male FCU	1127.0 (158.9 to 7993.9)*	0.00*	83.3% (36.1 to 97.2)	100.0% (99.7 to 100)		
Stewart et al, 2012[35]	AC2 Site: endocervical	Unable to calculate	0.10 (0.04 to 0.25)*	100.0% (90.2 to 100.0)*	99.8% (99.5 to 100.0)*	None reported (GenProbe provided supplies)	Good
	AC2 Site: self-collected vaginal	Unable to calculate	0.03 (0.00 to 0.17)*	100.0% (90.9 to 100.0)*	100.0% (99.8 to 100.0)*		
Taylor et al, 2012[32]	c4800 Site: FCU	Unable to calculate	0.00*	100% (58.9 to 100.0)*	100.0% (99.2 to 100.0)*	Roche Molecular Systems	Fair
	AC2 Site: FCU	Unable to calculate	0.00*	100% (58.9 to 100.0)*	100.0% (99.2 to 100.0)*		
	AC2 Site: urethral swab	Unable to calculate	0.00*	100% (58.9 to 100.0)*	100.0% (99.2 to 100.0)*		
	CT/GC Q^X Site: FCU	465.0 (65.6 to 3294.2)*	0.00*	87.5% (47.4 to 97.9)*	100.0% (99.2 to 100.0)*		
	CT/GC Q^X Site: urethral swab	Unable to calculate	0.00*	100% (58.9 to 100.0)*	100.0% (99.2 to 100.0)*		
Van Der Pol et al, 2012[33]	c4800 Site: endocervical	Unable to calculate	0.04 (0.01 to 0.30)*	100.0% (84.4 to 100.0)*†	100.0% (99.8 to 100.0)*	Roche Molecular Systems	Fair
	c4800 Site: FCU	2256.0 (317.9 to 16009.1)*	0.00*	95.8% (78.8 to 99.3)*	100.0% (99.8 to 100.0)*		
	AC2 Site: endocervical	Unable to calculate	0.00*	100.0% (85.1 to 100.0)	100.0% (99.8 to 100.0)*		
	AC2 Site: FCU	2170.4 (305.3 to 15431.2)*	0.04 (0.01 to 0.30)*	95.7% (78.0 to 99.3)*	100.0% (99.8 to 100.0)*		
	CT/GC Q^X Site: endocervical	512.5 (190.9 to 1375.3)*	0.09 (0.02 to 0.33)*	84.0% (63.9 to 95.4)*	99.9% (99.7 to 100.0)*		
	CT/GC Q^X Site: FCU	749.7 (242.0 to 2322.7)*	0.00*	88.5% (69.8 to 97.4)*	100.0% (99.8 to 100.0)*		
Van Der Pol et al, 2012[34]	GCQ Site: endocervical	203.7 (51.0 to 813.3)*	0.04 (0.01 to 0.25)*	92.9% (76.5 to 98.9)*	99.8% (98.7 to 100.0)*	BD Diagnostics	Fair
	GCQ Site: female FCU	211.5 (53.1 to 842.9)*	0.00*	93.1% (77.2 to 99.0)*	100.0% (99.1 to 100.0)*		
	GCQ Site: urethral swab	124.0 (46.7 to 329.1)*	0.00*	75.0% (47.6 to 92.6)*	100.0% (99.3 to 100.0)*		
	GCQ Site: male FCU	126.3 (47.6 to 335.1)*	0.00*	75.0% (47.6 to 92.6)*	100.0% (99.3 to 100.0)*		
	GCQ All female sites	127.7 (74.2 to 219.6)*	0.02 (0.00 to 0.07)*	89.1% (82.0 to 94.1)*	99.9% (99.6 to 100.0)*		
	GCQ All male sites	125.5 (71.4 to 220.5)*	0.00*	75.0% (60.4 to 86.4)*	100.0% (99.8 to 100.0)*		
	GCQ Overall	126.1 (85.3 to 186.4)*	0.01 (0.00 to 0.06)*	85.0% (78.7 to 90.1)*	99.9% (99.8 to 100.0)*		
	PTNG Site: endocervical	126.9 (40.9 to 393.7)*	0.07 (0.02 to 0.27)*	89.7% (72.6 to 97.7)*	99.5% (98.2 to 99.9)*		

Appendix C5. Diagnostic Accuracy Studies of Gonorrhea Tests

Study, year	Screening test	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)	Sponsor	Quality rating
	PTNG Site: female FCU	170.9 (42.4 to 688.3)*	0.18 (0.08 to 0.40)*	92.0% (73.9 to 98.8)*	98.8% (97.2 to 99.6)*		
	PTNG Site: urethral swab	Unable to calculate	0.00*	100.0% (73.4 to 100.0)*	100.0% (99.2 to 100.0)*		
	PTNG Site: male FCU	459.7 (64.5 to 3277.6)*	0.08 (0.01 to 0.51)*	92.3% (63.9 to 98.7)*	99.8% (98.9 to 100.0)*		
	PTNG All female sites	144.6 (60.0 to 348.3)*	0.13 (0.06 to 0.25)*	90.7% (79.7 to 96.9)*	99.2% (98.3 to 99.7)*		
	PTNG All male sites	938.9 (132.2 to 6669.6)*	0.04 (0.01 to 0.27)*	96.0% (79.6 to 99.3)*	99.9% (99.4 to 100.0)*		
	PTNG Overall	271.0 (121.5 to 604.3)	0.10 (0.05 to 0.19)*	92.4% (84.2 to 97.1)*	99.6% (99.1 to 99.8)*		
	AC2 Site: endocervical	202.5 (50.7 to 808.5)*	0.04 (0.01 to 0.25)*	93.1% (77.2 to 99.0)*	99.8% (98.7 to 100.0)*		
	AC2 Site: female FCU	Unable to calculate	0.21 (0.11 to 0.44)*	100.0% (84.4 to 100.0)*	98.6% (97.0 to 99.5)*		
	AC2 Site: urethral swab	118.3 (44.6 to 313.8)*	0.00*	73.3% (44.9 to 92.1)*	100.0% (99.2 to 100.0)*		
	AC2 Site: male FCU	168.3 (54.5 to 520.2)*	0.00*	80.0% (51.9 to 95.4)*	100.0% (99.3 to 100.0)*		
	AC2 All female sites	368.4 (92.0 to 1475.8)*	0.13 (0.06 to 0.25)*	96.1% (86.5 to 99.4)*	99.2% (98.3 to 99.7)*		
	AC2 All male sites	139.7 (66.8 to 292.3)*	0.00*	76.7% (57.7 to 90.0)*	100.0% (99.6 to 100.0)*		
	AC2 Overall	184.3 (95.7 to 354.9)*	0.09 (0.04 to 0.18)*	88.9% (80.0 to 94.8)*	99.6% (99.2 to 99.8)*		

* Calculated.

† Authors estimate PPV = 93.8% to 99.9% (based on hypothetical prevalence range of 1% to 50%).

Abbreviations: AC2 = Aptima Combo 2; AGC = Aptima NG test; BD = Becton Dickinson; c4800= cobas 4800 CT and NG test; CI = confidence interval; CT = *Chlamydia trachomatis*; CT/GC Q^x = BD ProbeTech CT and NG Q^x amplified DNA assay; FCU = first-catch urine; GCQ = BD ProbeTec NG Q^x amplified DNA assay on Viper system; IRB = institutional review board; NAAT = nucleic acid amplification test; NG = *Neisseria gonorrhea*; NR = not reported; PPV = positive predictive value; PTGC = BD ProbeTech ET for CT and NG; PTNG = BD ProbeTech ET NG amplified DNA assay; STI = sexually transmited infection.

Appendix C6. Diagnostic Accuracy Studies of Chlamydia Tests

Study, year	Screening test(s)	Definition of a positive screening exam	Reference standard(s)	Country Setting Prevalence
NAATs vs. NAATs				
Chernesky et al, 2005[31]	ACT Site: urethral swab, FCU	Positive result from at least 1 NAAT in both urethral swab and FCU; or one specimen positive on both NAATs	AC2 PTGC	Canada, U.S. STI clinics
Gaydos et al, 2013[36]	Xpert Site: self-collected vaginal, cervix, female FCU, male FCU	Positive result from at least 1 of the reference NAATs	AC2 PTGC	U.S. STI clinics
Schachter et al, 2003[37]	ACT, Amplicor Site: FCU, cervix, clinician-collected vaginal, self-collected vaginal	Agreement between positive results with vaginal swab and cervical swab or FCU	Culture	U.S., Canada Family planning, obstetrics/gynecology, and STI clinics CT prevalence across sites: 5.4% to 10.2% by culture
Schoeman et al, 2012[40]	AC2 Site: endocervix, self-collected vaginal	Positive result from 1 NAAT confirmed by second NAAT	Aptima CT	United Kingdom Sexual health clinic Prevalence: NR
Shrier et al, 2004[38]	Amplicor Site: endocervix, FCU, clinician-collected vaginal, self-collected vaginal	1 positive culture or 2 positive nonculture tests or 1 positive nonculture test confirmed by nested PCR	Culture Amplicor Abbot LCx assay	U.S. University medical center and children's hospital 21.6% positive for CT at any site
Taylor et al, 2012[32]	c4800 Site: FCU AC2, CT/GC Q^x Site: FCU, urethral swab	Positive result from ≥2 NAATs with different target regions in urethral swab and/or FCU	AC2 CT/GC Q^x	U.S. Obstetrics/gynecology, family planning, and STI clinics Prevalence ≥1%
Taylor et al, 2011[39]	CTQ, PTCT, AC2 Site: endocervical, female FCU, urethral swab, male FCU, all female sites, all male sites	≥1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays	AC2 PTCT	U.S. Family planning, obstetrics/gynecology, and STI clinics CT prevalence across sites: 11.6% in females, 21.4% in males
Van Der Pol et al, 2012[33]	c4800, AC2, CT/GC Q^x Site: endocervical, FCU	Positive result from ≥2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs	AC2 CT/GC Q^x	U.S. Family planning, obstetrics/gynecology, and STI clinics Prevalence NR

Study, year	Population Characteristics	Eligibility Criteria	Sample size Proportion with condition
NAATs vs. NAATs			
Chernesky et al, 2005[31]	Age (mean): 28.5 y 100% male 62.2% non-Hispanic black, 24.6% white	Men ages 15 to 77 y. Excluded if they could not concurrently provide all samples, had urinated within 1 hour, had taken antibiotics in the last 21 days, or if they could not provide informed consent.	1322 enrolled 17.9% CT 13.8% NG
Gaydos et al, 2013[36]	Age: ≥14 y (range or mean NR) 45% male (full sample, asymptomatic information NR separately) Race: NR	Age ≥14 y, sexually active in the last 6 months, and attending a participating clinic. Excluded if enrolled in previous trial, received antimicrobial therapy within 21 days of study, or history of hysterectomy.	2,270 asymptomatic 3.5% CT 0.7% NG

Appendix C6. Diagnostic Accuracy Studies of Chlamydia Tests

Study, year	Population Characteristics	Eligibility Criteria	Sample size Proportion with condition
Schachter et al, 2003[37]	Age (range): 16 to 25 y 100% female Race: NR	Females ages 16 to 25 y who were not pregnant and attending a study clinic for routine exam or birth control advice. Excluded if they had been treated with antibiotics within the last 30 days, were attending the clinic because of symptoms, or had a male partner treated for genital symptoms.	2517 tested 9.6% of women with CT by culture of 1 specimen
Schoeman et al, 2012[40]	Age (mean): 25 y 100% female Ethnicity: 80% white, 9% black, 7% mixed, 4% other	Women age ≥16 y presenting to study clinic for a new visit. Excluded if used antibiotics in the preceding 28 days, were unable or unwilling to perform self-taken swab, or have the standard exam and swabs performed by clinicians.	3973 enrolled 10.3% with CT
Shrier et al, 2004[38]	Age (mean): 19 y 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 ages 16 to 25 y who had ever had sexual intercourse, did not report symptoms of an STI, and were being seen at clinic for routine gynecologic care. Excluded if they were pregnant, had taken antibiotics in the previous 21 days, were diagnosed with CT in the previous 6 weeks, or had 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)
Taylor et al, 2012[32]	Age: 55% ≤30 y 100% male Race: 64.7% black, 32.9% white, 0.4% Asian, 0.4% American Indian/Alaskan Native, 0.1% Hawaiian/Pacific Islander, 1.3% other, 0.1% unknown Ethnicity: 82.7% non-Hispanic, 15.1% Hispanic, 2.2% unknown ethnicity	Men age ≥14 y. Excluded if they had been previously enrolled in the study or used antimicrobials effective against CT or NG in the preceding 21 days.	768 enrolled 16.4% CT 9.2% NG
Taylor et al, 2011[39]	Age (range): 17 to 64 y 32% male Race: NR Note: 2.7% of females were pregnant	Men and women ages 17 to 64 y who presented with urogenital symptoms or were being screened for CT and NG. Excluded if they had taken antibiotics in the previous 21 days, urinated in the previous hour, had sample collection issues, did not provide informed consent, or were younger than the age required by the site's IRB.	1538 enrolled 11.6% of females with CT 21.4% of males with CT
Van Der Pol et al, 2012[33]	Age: ≥14 y 100% female 43.1% black, 48.4% white, 22.1% Hispanic, 2.8% Asian/Pacific Islander, 5.7% other	Women age ≥14 y who were eligible for routine CT/NG screening as per standard practice at each enrollment site. Excluded if they had been previously enrolled, used antimicrobial agents active against CT or NG in preceding 21 days, used Raplense, a vaginal lubricant, within the past 3 days, or had a history of hysterectomy or contraindication to Pap test/cervical sampling.	4479 enrolled 6.3% CT 1.5% NG

Appendix C6. Diagnostic Accuracy Studies of Chlamydia Tests

Study, year	Screening test(s)	Proportion unexaminable by screening test	Number of indeterminate results	Proportion who underwent reference standard and included in analysis	True positives	False positives	False negatives	True negatives	Sensitivity (95% CI)
NAATs vs. NAATs									
Chernesky et al, 2005[31]	ACT Site: urethral swab	NR	NR	100%	94	16	1	634	98.9% (94.3 to 100)
	Site: FCU				94	19	1	638	98.9% (94.3 to 100)
Gaydos et al, 2013[36]	Xpert Site: self-collected vaginal	NR	0.25% (total sample) were invalid and unreadable	99.6%	48	7	1	1076	98.0% (89.1 to 99.9)
	Site: cervix				46	6	2	1074	95.8% (85.7 to 99.5)
	Site: female FCU				49	2	2	1083	96.1% (86.5 to 99.5)
	Site: male FCU				29	1	0	1102	100% (90.2 to 100)
Schachter et al, 2003[37]	ACT Site: FCU	Not reported	Not reported	Unclear	86*	7	33*	1265*	72.0%
	Site: cervix				106*	10	13*	1262*	89.1%
	Site: clinician-collected vaginal				107*	9	12*	1263*	89.9%
	Site: self-collected vaginal				111*	6	8*	1266*	93.3%
	Amplicor Site: FCU				63*	5	12*	501*	84.0%
	Site: cervix				68*	3	7*	503*	90.7%
	Site: clinician-collected vaginal				70*	6	5*	500*	93.3%
	Site: self-collected vaginal				68*	5	7*	501*	90.7%
Schoeman et al, 2012[40]	AC2 Site: endocervix	0.7%	4	97.3%	163	0	20	2050	89.0% (84.0 to 93.0)
	Site: self-collected vaginal				178	1	5	2049	97.0% (94.0 to 99.0)
Shrier et al, 2004[38]	Amplicor Site: endocervix	1 participant excluded because no samples were collected by physician	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)
	Site: FCU				12	0	15	99	44.4% (26.9 to 63.6)
	clinician-collected vaginal				15	0	12	99	55.6% (36.4 to 73.1)
	self-collected vaginal				14	1	13	98	51.9% (32.0 to 71.3)
Taylor et al, 2012[32]	c4800 Site: FCU	2.9%	NR	97.1%	51	2	1	418	98.1% (89.9 to 99.7)
	AC2 Site: FCU				50	4	1	417	98.0% (89.7 to 99.7)
	Site: urethral swab				48	5	3	416	94.1% (84.1 to 98.0)
	CT/GC Q[x] Site: FCU				50	2	2	418	96.2% (87.0 to 98.9)
	Site: urethral swab				45	1	7	419	86.5% (74.7 to 93.3)

Appendix C6. Diagnostic Accuracy Studies of Chlamydia Tests

Study, year	Screening test(s)	Proportion unexaminable by screening test	Number of indeterminate results	Proportion who underwent reference standard and included in analysis	True positives	False positives	False negatives	True negatives	Sensitivity (95% CI)
Taylor et al, 2011[39]	CTQ Site: endocervical	4.7%; 13% of men had only 2 urethral swabs collected rather than 3	19 unable to calculate from PTCT; 7/19 resolved negative All 19 were negative by CTQ and AC2	95.3%	53	8	4	385	93.0% (83.0 to 98.1)
	Site: female FCU				54	2	3	391	94.7% (85.4 to 98.9)
	Site: urethral swab				31	2	4	178	88.6% (73.3 to 96.8)
	Site: Male FCU				35	2	0	178	100.0% (90.0 to 100.0)
	All female sites				216	12	12	1559	94.7% (91.0 to 97.3)
	All male sites				101	6	4	534	96.2% (90.5 to 99.0)
	PTCT Site: endocervical				51	0	8	379	86.4% (75.0 to 94.0)
	Site: female FCU				53	1	6	384	89.8% (79.2 to 96.2)
	Site: urethral swab				31	2	5	173	86.1% (70.5 to 95.3)
	Site: male FCU				35	1	1	173	97.2% (85.5 to 99.9)
	All female sites				104	1	14	763	88.1% (80.9 to 93.4)
	All male sites				66	3	6	346	91.7% (82.7 to 96.9%)
	AC2 Site: endocervical				52	4	4	389	92.9% (82.7 to 98.0)
	Site: female FCU				55	2	1	392	98.2% (90.4 to 100.0)
	Site: urethral swab				30	2	3	166	90.9% (75.7 to 98.1)
	Site: male FCU				35	0	1	179	97.2% (85.5 to 99.9)
	All female sites				107	6	5	781	95.5% (89.9 to 98.5)
	All male sites				65	2	4	345	94.2% (85.8 to 98.4)
Van Der Pol et al, 2012[33]	c4800 Site: endocervical	3.6% of enrolled; 16.4% for primary analysis of particular specimen type	NR	96.4%	94	1	11	2163	89.5% (82.2 to 94.0)
	Site: FCU				98	4	12	2165	89.1% (81.9 to 93.6)
	AC2 Site: endocervical				101	12	3	2173	97.1% (91.9 to 99.0)
	Site: FCU				98	5	8	2181	92.5% (85.8 to 96.1)
	CT/GC Q[x] Site: endocervical				102	7	4	2155	96.2% (90.7 to 98.5)
	Site: FCU				101	6	4	2161	96.2% (90.6 to 98.5)

Study, year	Screening test(s)	Specificity (95% CI)	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)	Sponsor	Quality rating
NAATs vs. NAATs								
Chernesky et al, 2005[31]	ACT Site: urethral swab	97.5% (96.0 to 98.6)	40.2 (24.8 to 65.3)*	0.01 (0.00 to 0.08)*	85.5% (77.5 to 91.5)*	99.8% (99.1 to 100)*	NR	Fair
	ACT Site: FCU	98.0% (96.6 to 98.9) 97.1% (95.5 to 98.3)*	34.2 (22.0 to 53.3)*	0.01 (0 to 0.08)*	83.2% (75 to 89.6)*	99.8% (99.1 to 100)*		
Gaydos et al, 2013[36]	Xpert Site: self-collected vaginal	99.4% (98.7 to 99.7)	151.6 (72.3 to 317.5)*	0.02 (0.00 to 0.14)*	87.3% (75.5 to 94.7)	99.9% (99.5 to 99.9)	Cepheid, grant from National Insitute of Biomedical Imaging and Bioengineering	Fair
	Site: cervix	99.4% (98.8 to 99.8)	172.5 (77.5 to 383.9)*	0.04 (0.01 to 0.16)*	88.5% (76.5 to 95.6)	99.8% (99.3 to 99.7)		
	Site: female FCU	99.8% (99.3 to 100)	521.2 (130.4 to 2083.8)*	0.04 (0.01 to 0.15)*	96.1% (86.5 to 99.4)	99.8% (99.3 to 99.9)		
	Site: male FCU	99.9% (99.5 to 100)	1103.0 (155.5 to 7823.6)*	0.00*	96.7% (82.7 to 99.4)	100% (99.6 to 100)		

Appendix C6. Diagnostic Accuracy Studies of Chlamydia Tests

Study, year	Screening test(s)	Specificity (95% CI)	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)	Sponsor	Quality rating
Schachter et al, 2003[37]	ACT Site: FCU	99.5%	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)*	Roche Molecular Systems; Abbott Laboratories; GenProbe, Inc; CDC	Fair
	Site: cervix	99.3%	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)*		
	Site: clinician-collected vaginal	99.4%	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)*		
	Site: self-collected vaginal	99.6%	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)		
	Amplicor Site: FCU	99.0%	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)*		
	Site: cervix	99.4%	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)*		
	Site: clinician-collected vaginal	98.8%	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)*		
	Site: self-collected vaginal	99.0%	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)*		
Schoeman et al, 2012[40]	AC2 Site: endocervix	100% (99.8 to 100.0)	Unable to calculate	0.11 (0.07 to 0.17)*	100.0% (97.7 to 100.0)*	99.0% (98.5 to 99.4)*	None reported (GenProbe provided supplies)	Good
	Site: self-collected vaginal	99.9% (99.7 to 100.0)	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)*		
Shrier et al, 2004[38]	Amplicor Site: endocervix	100% (96.5 to 100)	Unable to calculate	0.48 (0.33 to 0.71)*	100% (77.0 to 100)	88.4% (81.1 to 93.6)	Roche Molecular Systems, Inc; CDC; NIMH, NIH	Good
	Site: FCU	100% (96.5 to 100)	0.56 (0.40 to 0.78)	Unable to calculate	100% (76.4 to 100)	86.8% (79.6 to 92.3)		
	Site: clinician-collected vaginal	100% (96.5 to 100)	Unable to calculate	0.44 (0.29 to 0.68)*	100% (78.7 to 100)	89.2% (82.4 to 94.0)		
	Site: self-collected vaginal	99.0% (95.0 to 100)	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)		
Taylor et al, 2012[32]	c4800 Site: FCU	99.5% (98.3 to 99.9)	206.0 (51.7 to 821.3)*	0.02 (0.00 to 0.13)*	96.2% (87.0 to 99.4)*	99.8% (98.7 to 100.0)*	Roche Molecular Systems	Fair
	AC2 Site: FCU	99.0% (97.6 to 99.6)	103.2 (38.9 to 273.9)*	0.02 (0.00 to 0.14)*	92.6% (82.1 to 97.9)*	99.8% (98.7 to 100.0)*		
	Site: urethral swab	98.9% (97.3 to 99.5)	79.3 (33.1 to 189.9)*	0.06 (0.02 to 0.18)*	90.6% (79.3 to 96.8)*	99.3% (97.9 to 99.8)*		
	CT/GC Q[x] Site: FCU	99.5% (98.3 to 99.9)	201.9 (50.6 to 805.6)*	0.04 (0.01 to 0.15)*	96.2% (86.8 to 99.4)*	99.5% (98.3 to 99.9)*		
	Site: urethral swab	99.8% (98.7 to 100.0)	363.5 (51.2 to 2581.9)*	0.13 (0.07 to 0.27)*	97.8% (88.4 to 99.6)*	98.4% (96.6 to 99.3)*		
	CTQ Site: endocervical	98.0% (96.0 to 99.1)	45.7 (22.3 to 91.0)*	0.07 (0.03 to 0.18)*	86.9% (75.8 to 94.2)*	99.0% (97.4 to 99.7)*	BD Diagnostics	Fair
	Site: female FCU	99.5% (98.2 to 99.9)	186.2 (46.7 to 742.7)*	0.05 (0.02 to 0.16)*	96.4% (87.7 to 99.5)*	99.2% (97.8 to 99.8)*		
	Site: urethral swab	98.9% (96.0 to 99.9)	79.7 (20.0 to 317.9)*	0.12 (0.05 to 0.29)*	93.9% (79.7 to 99.1)*	97.8% (94.5% to 99.4)*		
	Site: Male FCU	98.9% (96.0 to 99.9)	90.0 (22.7 to 357.1)*	0.00*	94.6% (81.8 to 99.2)*	100.0% (97.9 to 100.0)*		
	All female sites	99.2% (98.7 to 99.6)	124.0 (70.5 to 218.1)*	0.05 (0.03 to 0.09)*	94.7% (91.0 to 97.3)*	99.2% (98.7 to 99.6)*		
	All male sites	98.9% (97.6 to 99.6%)	86.6 (39.0 to 192.0)*	0.04 (0.01 to 0.10)*	94.4% (88.2 to 97.9)*	99.3% (98.1 to 99.8)*		
	PTCT Site: endocervical	100.0% (99.0 to 100.0)	Unable to calculate	0.14 (0.07 to 0.26)*	100.0% (93.0 to 100.0)*	97.9% (96.0 to 99.1)*		
	Site: female FCU	99.7% (98.6 to 100.0)	345.9 (48.8 to 2453.7)*	0.10 (0.05 to 0.22)*	98.2% (90.1 to 99.7)*	98.5% (96.7 to 99.4)*		
	Site: urethral swab	98.9% (95.9 to 99.9)	75.4 (18.9 to 300.8)*	0.14 (0.06 to 0.32)*	93.9% (79.7 to 99.1)*	97.2% (93.6 to 99.1)*		
	Site: male FCU	99.4% (96.8 to 100.0)	169.2 (23.9 to 1195.2)*	0.03 (0.00 to 0.19)*	97.2% (85.4 to 99.5)*	99.4% (96.8 to 99.9)*		
	All female sites	99.9% (99.3 to 100.0)	673.4 (94.9 to 4779.6)*	0.12 (0.07 to 0.19)*	99.1% (94.8 to 99.8)*	98.2% (97.0 to 99.0)*		
	All male sites	99.1% (97.5 to 99.8)	106.6 (34.5 to 329.8)*	0.08 (0.04 to 0.18)*	95.6% (87.8 to 99.0)*	98.3% (96.3 to 99.4)*		
	AC2 Site: endocervical	99.0% (97.4 to 99.7)	91.2 (34.3 to 242.5)*	0.07 (0.03 to 0.19)*	92.9% (82.7 to 98.0)*	99.0% (97.4 to 99.7)*		
	Site: female FCU	99.5% (98.2 to 99.9)	193.5 (48.5 to 771.3)*	0.02 (0.00 to 0.13)*	96.5% (87.9 to 99.5)*	99.8% (98.6 to 100.0)*		

Appendix C6. Diagnostic Accuracy Studies of Chlamydia Tests

Study, year	Screening test(s)	Specificity (95% CI)	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)	Sponsor	Quality rating
Taylor et al, 2011[39]	AC2 Site: urethral swab	98.8% (95.8 to 99.9)	76.4 (19.2 to 304.1)*	0.09 (0.03 to 0.27)*	93.8% (79.2 to 99.1)*	98.2% (94.9 to 99.6)*	BD Diagnostics	Fair
	Site: male FCU	100.0% (98.0 to 100.0)	Unable to calculate	0.03 (0.00 to 0.19)*	100.0% (89.9 to 100.0)*	99.4% (96.9 to 99.9)*		
	All female sites	99.2% (98.3 to 99.7)	125.3 (56.4 to 278.4)*	0.04 (0.02 to 0.11)*	94.7% (88.8 to 98.0)*	99.4% (98.5 to 99.8)*		
	All male sites	99.4% (97.9 to 99.9)	163.4 (41.0 to 651.7)*	0.06 (0.02 to 0.15)*	97.0% (89.6 to 99.6)*	98.9% (97.1 to 99.7)*		
Van Der Pol et al, 2012[33]	c4800 Site: endocervical	100.0% (99.7 to 100.0)	1937.3 (272.7 to 13762.3)*	0.10 (0.06 to 0.18)*	99.0% (94.3 to 99.8)* Note: authors estimate PPV of 77.3% to 99.7% (based on hypothetical prevalence range of 1% to 50%)	99.5% (99.1 to 99.8)*	Roche Molecular Systems	Fair
	Site: FCU	99.8% (99.5 to 99.9)	483.1 (181.1 to 1288.8)*	0.11 (0.06 to 0.19)*	96.1% (90.3 to 98.9)*	99.5% (99.0 to 99.7)*		
	AC2 Site: endocervical	99.5% (99.0 to 99.7)	176.8 (100.5 to 311.2)*	0.03 (0.01 to 0.09)*	89.4% (82.2 to 94.4)*	99.9% (99.6 to 100.0)*		
	Site: FCU	99.8% (99.5 to 99.9)	404.2 (168.1 to 971.8)*	0.08 (0.04 to 0.15)*	95.2% (89.0 to 98.4)*	99.6% (99.3 to 99.8)*		
	CT/GC Q[x] Site: endocervical	99.7% (99.3 to 99.8)	297.2 (141.7 to 623.3)*	0.04 (0.01 to 0.10)*	93.6% (87.2 to 97.3)*	99.8% (99.5 to 100.0)*		
	Site: FCU	99.7% (99.4 to 99.9)	347.4 (156.1 to 773.1)*	0.04 (0.01 to 0.10)*	94.4% (88.2 to 97.9)*	99.8% (99.5 to 100.0)*		

* Calculated.

Abbreviations: AC2 = Aptima Combo 2; ACT = Aptima *Chlamydia trachomatis* test; Amplicor = Roche cobas Amplicor test; BD = Becton Dickinson; c4800= Roche cobas 4800 CT and NG test; CDC = Centers for Disease Control and Prevention; CI = confidence interval; CT = *Chlamydia trachomatis*; CTQ = BD ProbeTec CT Qx amplified DNA assay on the Viper system; CT/GC Qx = BD ProbeTec CT and NG Qx amplified DNA assay; EIA = enzyme immunoassay; FCU = first-catch urine; IRB = institutional review board; NAAT = nucleic acid amplification test; NG = *Neisseria gonorrhea*; NIH = National Institutes of Health; NIMH = National Institute for Mental Health; NR = not reported; PCR = polymerase chain reaction; PT = ProbeTech; PTCT = BD ProbeTech ET CT amplified DNA assay; PTGC = BD ProbeTech ET amplified DNA assay for CT and NG; STI = sexually transmitted infection.

Appendix C7. Quality Ratings of Diagnostic Accuracy Studies

Study, year	Representative spectrum	Random or consecutive sample	Screening test adequately described	Screening cutoffs predefined	Credible reference standard	Reference standard applied to and analysis includes all patients, or a random subset	Same reference standard applied to all patients	Reference standard and screening examination interpreted independently	High rate of uninterpretable results or noncompliance with screening test	Analysis includes patients with uninterpretable results or noncompliance	Quality Rating
Chernesky et al, 2005[31]	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear	Unclear	Fair
Schacter et al, 2003[37]	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear	Unclear	Fair
Schoeman et al, 2012[40]	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Unclear	No	Yes	Good
Shrier et al, 2004[38]	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Unclear	No	No	Fair
Stewart et al, 2012[35]	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Unclear	No	Yes	Good
Taylor et al, 2011[39]	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Unclear	No	Unclear	Fair
Taylor et al, 2012[32]	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Unclear	No	No	Fair
Van Der Pol et al, 2012[33]	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Unclear	No	Unclear	Fair
Van Der Pol et al, 2012[34]	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Unclear	No	Unclear	Fair
Gaydos et al, 2013[36]	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Unclear	No	Unclear	Fair