

# Selective Testing Criteria for Gonorrhea among Young Women Screened for Chlamydial Infection: Contribution of Race and Geographic Prevalence

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**Background.** Selective screening criteria have been widely implemented for genital *Chlamydia trachomatis* (CT) infections but have rarely been developed for *Neisseria gonorrhoeae* (GC) infection.

**Methods.** Women tested for CT in Washington State Infertility Prevention Project clinics in 2003 were also tested for GC using the Gen-Probe APTIMA COMBO 2 TMA assay. We derived 3 sets of selective testing criteria (STC) for gonorrhea, incorporating risk factors identified using logistic regression (STC-1), self-identified race (STC-2), and local rates of gonorrhea in men (STC-3).

**Results.** Of 55,781 women, 173 (0.3%) tested positive for GC. STC-1 included exposure to sexually transmitted diseases, presumptive CT treatment at screening, a pregnancy-related visit, report of a symptomatic partner, dysuria, abnormal vaginal discharge, or a new sex partner during the preceding 60 days. These criteria identified 80% of cases while testing 47% of women. STC-2 added race (black/Native American) to STC-1 and identified 89% of cases while testing 52%. STC-3 added clinic location in a ZIP code area with male urethral GC infection rates in the top quartile of Washington State rates to STC-1 and identified 86% of cases while testing 58%.

**Conclusions.** Although testing criteria incorporating race were most specific, criteria including local area rates of GC infection in men had similar sensitivity and required testing only slightly more women.

Screening for asymptomatic infections has been a cornerstone of public health efforts to control bacterial sexually transmitted diseases (STDs). In the United States, widespread screening programs for syphilis were established in the 1940s [1]. Screening programs for *Neisseria gonorrhoeae* were initiated in the 1970s [2], and those for *Chlamydia trachomatis* began in the late 1980s [3–5]. Although screening for gonococcal and chlamydial infections has been integrated into many public and private sector settings, only chlamydial

screening programs have benefited from carefully defined selective screening criteria [6–8]. Although the US Preventive Services Task Force (USPSTF) has developed guidelines for gonorrhea screening [9], they are based on an evaluation of the literature rather than on empiric analyses explicitly seeking to identify screening criteria.

Nucleic acid–amplification tests (NAATs) have become the most commonly used assays for chlamydial and gonococcal infection [10], and several commercially available NAATs now test simultaneously for both *N. gonorrhoeae* and *C. trachomatis*. Although these assays are generally very specific, the prevalence of *N. gonorrhoeae* in US women is less than one-fifth that of *C. trachomatis* [11, 12] and in most screened populations is <1% [12–14]. In such settings, the positive predictive value for assays used to diagnose gonococcal infection may be poor, even for highly specific NAATs [15], prompting some authorities to recommend routine confirmatory testing of all positive specimens [16].

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Selectively testing only women at the highest risk for gonorrhea may diminish the risk of false-positive results and provide cost savings [17].

Logical candidates for testing criteria include established risk factors for prevalent infection, similar to the approach used to develop screening criteria for *C. trachomatis*. Although gonococcal infections have been associated with young age, low socioeconomic status, an early onset of sexual activity, single marital status, a history of gonococcal infection, illegal drug use, and commercial sex work [18], the strongest and most consistent predictor of gonorrhea in most US studies has been black race. Testing women for gonorrhea on the basis of race could efficiently identify many individuals at an elevated risk of infection and direct them toward appropriate care. However, the practice could be stigmatizing and difficult to systematically institute. An alternative is targeting high-prevalence geographic areas for screening. Most US populations live in highly segregated communities ([http://www.census.gov/hhes/immigration/diversity/diversity/chart\\_dissimilarity.html](http://www.census.gov/hhes/immigration/diversity/diversity/chart_dissimilarity.html)), and previous studies have demonstrated that gonorrhea is geographically concentrated [19]. We used data from the Region X Infertility Prevention Project (IPP) to develop selective testing criteria for gonorrhea and compare the utility of adding race versus local area geographic prevalence.

## SUBJECTS AND METHODS

**Study population.** The IPP is a Centers for Disease Control and Prevention program that funds chlamydial testing throughout the United States [20]. In 2003, laboratories serving IPP clinics in Washington State began using the APTIMA COMBO 2 TMA assay (Gen-Probe) to provide *N. gonorrhoeae* test results to women screened for *C. trachomatis*. Women attending IPP family-planning clinics ( $n = 47,280$ ), women's clinics ( $n = 3677$ ), community clinics ( $n = 4812$ ), and school- or college-based clinics ( $n = 3561$ ) in 2003 who met selective screening criteria for chlamydial infection (e.g., age <25 years, reason for visit, history of STD, condom use, sexual risk behaviors, and reported symptoms) were included. Those attending STD clinics ( $n = 2381$ ), HIV counseling and testing centers ( $n = 180$ ), and clinics in corrections facilities ( $n = 1859$ ) were excluded, given the higher prevalence of STDs and sexual risk behaviors in these populations.

**Data collection.** IPP clients received a clinical examination during which either a cervical or urethral swab or a urine specimen was obtained. All sites used a common laboratory slip collecting information about age, race (self-reported), ethnicity, clinical findings, sexual risk behaviors (self-reported), and chlamydia diagnoses during the preceding year. Clinicians routinely recorded whether patients had been exposed to an STD other than *C. trachomatis* but did not specifically note exposure to *N. gonorrhoeae*.

**Geographic measures.** Each IPP clinic was given an anon-

ymous identifier and coded by ZIP code. Each woman was assigned the ZIP code of the clinic she attended. The local area prevalence of *N. gonorrhoeae* infection was estimated using 2002 Washington State rates of male gonococcal urethritis (case totals aggregated by ZIP code; provided by M. Stenger, Washington State Department of Health, Olympia). Rates for each ZIP code that included an IPP clinic were calculated by dividing the number of reported cases by the ZIP code tracking area population size from the 2000 US Census ([http://factfinder.census.gov/home/saff/main.html?\\_lang=en](http://factfinder.census.gov/home/saff/main.html?_lang=en)).

**Statistical methods.** Univariate descriptive statistics were calculated using Pearson's  $\chi^2$  test. Multivariate logistic regression analyses done using Stata software (version 8.0; StataCorp) to identify risk factor-based selective testing criteria used generalized estimating equations to account for multiple visits by some women. A certificate of exemption for secondary analyses of anonymized data was obtained from the University of Washington Human Subjects Division in lieu of full institutional review board review.

## RESULTS

In 2003, 63,750 screening tests for *C. trachomatis* were performed in Washington IPP clinics. Of these, 56,059 (87.9%) were performed on cervical swab specimens, 7511 (11.8%) on urine specimens, 138 (0.2%) on urethral swab specimens, and 42 (0.1%) on other specimen types (e.g., rectal and pharyngeal swabs). After excluding STD clinics, HIV counseling and testing sites, and correctional facilities, 59,330 records remained. The prevalence of chlamydial infection was 6.0% (95% confidence interval [CI], 5.83%–6.22%), and a test result for *N. gonorrhoeae* was available for 94% ( $n = 55,781$ ). The prevalence of gonococcal infection was 0.3% (95% CI, 0.26%–0.36%).

**Characteristics of women.** The majority of women were screened in family-planning or women's clinics (84%), and most (83%) met chlamydia screening criteria on the basis of age (<25 years). These women were predominantly white (74.5%), and 8.3% were black. Hispanic ethnicity was reported by 14.7%. Although a small proportion reported having multiple sex partners during the preceding 60 days (8.4%), almost one-quarter reported having a new partner during that time period. Few women reported having a symptomatic partner during the preceding 60 days (3%), and only 25% had used a condom during their most recent sexual encounter. Self-reported history of STDs was relatively uncommon (8.4%), and 15.1% were pregnant at the time of the visit. The most frequent reason for the visit was STD screening (23%), and the most common symptom was abnormal vaginal discharge (12.5%); other symptoms of genital tract infection were rarely reported (<5% of women). Fewer than 2.5% attended because of suspected contact with an infected partner, and most had normal examination findings.

**Table 1. Subgroup prevalence and characteristics associated with gonococcal infection.**

Characteristic	Gonorrhea prevalence, %	Gonorrhea, no. (%) (n = 173)	No gonorrhea, no. (%) (n = 55,608)	P <sup>a</sup>
CT infection	2.2	75 (43.9)	3278 (5.9)	<.001
Clinic type				
Family-planning/women's clinics	0.3	145 (83.8)	48,196 (86.7)	.001
Community <sup>b</sup>	0.6	25 (14.5)	4386 (7.9)	
School/college-based clinics	0.1	3 (1.7)	3026 (5.4)	
Age				
<15 years	0.7	5 (2.9)	728 (1.3)	.03
15–19 years	0.4	78 (45.1)	21,450 (38.6)	
20–24 years	0.3	71 (41.0)	23,789 (42.8)	
25–29 years	0.1	6 (3.5)	4810 (8.7)	
≥30 years	0.3	13 (7.5)	4823 (8.7)	
Race <sup>c</sup>				
White	0.2	94 (56.6)	39,794 (74.6)	<.001
Black	1.1	48 (28.9)	4281 (8.0)	<.001
Asian	0.1	4 (2.4)	3860 (7.2)	.02
Native American	1.1	14 (8.4)	1324 (2.5)	<.001
Hawaiian/Pacific Islander	0.6	6 (3.6)	1042 (2.0)	.12
Other	0.2	11 (6.6)	4884 (9.2)	.26
Hispanic	0.3	23 (13.9)	7477 (14.4)	.85
Multiple sex partners <sup>d</sup>	0.7	33 (19.6)	4435 (8.3)	<.001
New sex partner <sup>d</sup>	0.5	62 (36.5)	11,945 (22.1)	<.001
Symptomatic partner <sup>d</sup>				
No	0.3	125 (72.7)	49,711 (91.2)	<.001
Yes	2.0	32 (18.6)	1600 (2.9)	
Don't know	0.5	15 (8.7)	3187 (5.9)	
History of STD during the preceding 12 months				
History of STD during the preceding 12 months	0.9	17 (10.1)	1879 (3.5)	<.001
Condom use at most recent sex	0.4	51 (30.4)	13,211 (24.9)	.11
Presumptive treatment for CT infection	1.0	47 (28.5)	4777 (9.2)	<.001
Reason for visit <sup>c</sup>				
Symptoms	0.5	46 (27.2)	8997 (16.5)	<.001
Exposed to CT	1.4	11 (6.5)	793 (1.5)	<.001
Exposed to an STD other than CT	5.6	22 (13.0)	374 (0.7)	<.001
Rescreening for CT	0.3	3 (1.8)	1085 (2.0)	.84
Pregnancy related	0.4	33 (19.5)	8322 (15.3)	.13
STD screen	0.4	57 (33.7)	12,835 (23.6)	.002
Signs of infection <sup>c</sup>				
Mucopurulent discharge	1.0	22 (16.2)	2246 (4.7)	<.001
Easily induced cervical bleeding	0.5	14 (10.3)	2646 (5.6)	.02
Ectopy/inflammation/edema	0.9	12 (8.8)	1343 (2.8)	<.001
Cervicitis <sup>e</sup>	0.6	33 (24.3)	5104 (10.7)	<.001
PID	0.4	1 (0.7)	266 (0.6)	.78
None: normal cervix	0.2	104 (76.5)	42,979 (90.3)	<.001
Symptoms <sup>c</sup>				
Abnormal vaginal discharge	0.7	51 (29.5)	6885 (12.4)	<.001
Dysuria	1.1	21 (12.1)	1937 (3.5)	<.001
Pelvic pain	0.6	15 (8.7)	2646 (4.8)	.02
Abnormal bleeding	0.4	8 (4.6)	1816 (3.3)	.32

**NOTE.** The denominators used to calculate percentages vary because data were not available for all subjects for all variables. CT, *Chlamydia trachomatis*; PID, pelvic inflammatory disease; STD, sexually transmitted disease.

<sup>a</sup> Pearson's  $\chi^2$  test.

<sup>b</sup> Includes adolescent not-in-school clinics, Indian Health, migrant, and community clinics.

<sup>c</sup> Comparison group consists of all individuals not in a given category.

<sup>d</sup> During the preceding 60 days.

<sup>e</sup> Mucopurulent discharge, ectopy with inflammation or edema, or easily induced cervical bleeding.

**Factors associated with gonococcal infection.** Because of our large sample size, most factors were significantly associated with gonococcal infection ( $P < .05$ ) (table 1). Risk factors for which the prevalence of *N. gonorrhoeae* was  $\geq 1\%$  included testing positive or receiving presumptive treatment for *C. trachomatis* at the visit, black or American Indian/Alaska Native race, a symptomatic partner during the preceding 60 days, exposure to a partner with *C. trachomatis* infection or another STD, mucopurulent cervical discharge, and dysuria.

**Geographic prevalence of *N. gonorrhoeae*.** Washington State rates of male urethral gonococcal infection calculated for each ZIP code were matched with the clinic ZIP codes and stratified into quartiles (0–23, 24–57, 58–118, and 119–1754 cases/100,000 men residing in the clinic ZIP code area). The proportion of gonorrhea cases in clinics in a given ZIP code rose as rates of male urethral gonococcal infection in that same ZIP code increased ( $P < .001$  for trend) (figure 1), reaching 0.36% in the top quartile.

**Development of selective testing criteria.** Under a risk factor–based strategy using multivariate logistic regression, the strongest predictor of *N. gonorrhoeae* infection was exposure to an STD other than *C. trachomatis* infection (table 2). Women who reported having a symptomatic partner, had complaints of dysuria or vaginal discharge, received presumptive therapy for *C. trachomatis* infection, attended for pregnancy-related reasons, or reported having a new partner during the preceding 60 days were also at a significantly elevated risk for gonorrhea. These characteristics formed the basic set of selective testing criteria (STC-1). Cervicitis was not independently associated with gonorrhea (odds ratio [OR], 1.1 [95% CI, 0.64–1.76]), and, because the vast majority (82.7%) of these women were <25 years old, age was not suitable as a testing criterion.

We next added black/Native American race to the risk factor–based criteria to generate a second set of criteria (STC-2), or race-based criteria. In this model, black and Native American women were 4.4 times more likely to have gonorrhea than were women of other race/ethnicities, and the base risk factors remained virtually unchanged.

In a third set of selective testing criteria (STC-3), we excluded the individual race criterion and incorporated the geographic prevalence of gonococcal infection. In this model, women attending clinics in geographic areas where the prevalence of urethral gonorrhea in men was in the top quartile of Washington State rates were 60% more likely to have a positive test for gonorrhea than were women in other areas. Similar to STC-2, the base risk factors remained virtually unchanged.

Finally, we limited our screening population to healthy women by excluding those with clinical signs of cervicitis or pelvic inflammatory disease (PID;  $n = 5694$  [10%]). The risk factor–based testing criteria identified in this restricted screening population were identical to those identified in the total

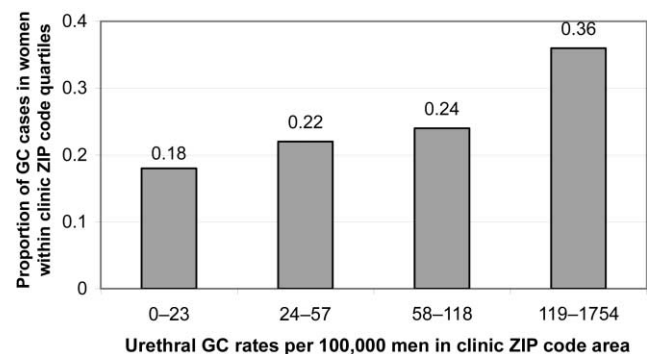
IPP population, as was the effect of adding race (data not shown). However, the local area prevalence of gonorrhea in men was no longer significantly associated with female gonorrhea (OR, 1.4 [95% CI, 0.96–2.19]).

**Comparison of selective testing criteria.** Implementing risk factor–based (STC-1) and race-based (STC-2) criteria would test ~50% of women, whereas using the geographic prevalence–based criteria (STC-3) would test slightly more (58%) (table 3). The proportion of cases identified was similar under race-based and geographic prevalence–based criteria (89% vs. 86%). The prevalence of gonorrhea among women who would not be tested under each set of criteria was <0.2% and was highest for the risk factor–based testing criteria. Geography-based testing would identify 85% of cases in black/Native American women (the highest risk group), whereas risk factor–based testing would identify 75% of such cases.

**Correlation between race and local prevalence.** Race was significantly associated with the local area prevalence of gonorrhea ( $P < .001$ ). Nearly half (47.5%) of black/Native American women with gonorrhea attended clinics in the top quartile of male urethral gonorrhea rates, whereas 29.5% attended clinics in the third quartile and 23% attended clinics in the bottom 2 quartiles. However, when race and local area gonorrhea prevalence were considered together in the risk factor model, only race remained significantly associated with gonorrhea (data not shown).

## DISCUSSION

Using a large and diverse clinical database of young women tested for genital chlamydial infection, we found that using selective testing criteria consisting of pregnancy, having a new sex partner or one with a known STD or symptoms suggestive of STD, and selected symptoms (dysuria or abnormal vaginal discharge) would identify 80% of cases of gonorrhea while eliminating testing in half the population. Including either patient race or information about rates of gonorrhea in the local



**Figure 1.** Correlation between male gonococcal infection rates by ZIP code and cases of *Neisseria gonorrhoeae* (GC) infection among women attending clinics in corresponding ZIP code areas.

**Table 2. Multivariate logistic regression models identifying selective testing criteria for gonorrhea (GC).**

Model	STC-1	STC-2	STC-3
Exposed to an STD other than CT	9.3 (5.2–16.7)	8.6 (4.6–15.8)	9.4 (5.2–17.1)
Symptomatic partner	3.2 (1.9–5.5)	3.3 (1.9–5.7)	3.3 (1.9–5.6)
Dysuria (complaint)	2.3 (1.3–4.2)	2.1 (1.2–3.9)	2.3 (1.3–4.1)
Presumptive treatment for CT infection	2.1 (1.4–3.1)	2.1 (1.4–3.1)	2.0 (1.3–3.1)
Abnormal vaginal discharge	2.0 (1.3–4.2)	1.8 (1.2–2.7)	1.9 (1.3–3.0)
Pregnancy-related visit	1.9 (1.3–3.0)	1.7 (1.1–2.7)	1.6 (1.0–2.6)
New partner during the preceding 60 days	1.7 (1.2–2.5)	1.7 (1.1–2.4)	1.8 (1.2–2.6)
Black/Native American	...	4.4 (3.1–6.3)	...
Clinic in top quartile of male urethral GC infection rates	...	...	1.6 (1.1–2.4)

**NOTE.** Data are adjusted odds ratio (95% confidence interval). CT, *Chlamydia trachomatis*; STC-1, selective testing criteria 1 (risk factor based); STC-2, selective testing criteria 2 (race based; STC-1 plus individual race); STC-3, selective testing criteria 3 (geography based; STC-1 plus local geographic prevalence in men); STD, sexually transmitted disease.

male population increased the proportion of cases identified and only increased the number of women tested by 5%–11%.

Rates of gonorrhea in the United States remain dramatically higher in blacks than in whites (626.4 vs. 35.2 cases/100,000 population in 2005) [12], and the concentrated nature of gonorrhea in this subpopulation suggests that race would be a good screening criterion. Indeed, adding race to the risk factor–based criteria increased sensitivity and was a more powerful predictor than local area prevalence. However, testing on the basis of race has the potential to be stigmatizing, operational definitions of race may vary from clinic to clinic (self-report vs. clinician assigned), and there is little to suggest that black Americans are genetically more susceptible to gonorrhea. Rather, the high rates are more likely the result of contextual characteristics such as poverty and incarceration [21], as well as a skewed male to female ratio that may promote concurrent sex partnerships [22].

Geographic segregation may also contribute to higher rates of gonorrhea in blacks, yet in Baltimore, Maryland, geographic clustering of cases of gonorrhea persisted after adjustment for race/ethnicity [19], which suggests an effect of geography above and beyond racial segregation. This contrasts with our data in which geographic location was not significantly associated with gonorrhea after adjustment for race. Although testing on the basis of race may begin to address the enormous racial disparities in STD rates [23], using the local prevalence of male

gonorrhea captured additional cases in nonblack individuals and may provide a more socially acceptable and equally sensitive criterion. Ultimately, the choice of race or local area prevalence as a testing criterion must be a local decision informed by discussions with the community. Making geography-based testing operational could be challenging but should be feasible. State or local health departments could publish an annual list of high-prevalence ZIP code areas and recommend universal screening in clinics within those ZIP codes.

We use the term “selective testing” rather than “selective screening” because we included women with clinical signs of infection in our analyses. Traditionally, women with clinical signs receive diagnostic testing and are excluded from screening considerations. However, the decreasing frequency of pelvic examinations associated with a broader uptake of urine-based testing, the absence of an independent association of clinical signs with gonococcal infection, and the low prevalence of gonorrhea among women with clinical signs (0.6%) suggests that criteria for selective testing may be more relevant.

Most previous studies of gonorrhea testing have focused on specialized populations with higher prevalences, such as incarcerated persons or emergency department attendees. Routine rather than selective screening is recommended in jails [24, 25], whereas screening a targeted age range of 15–30 years is recommended in emergency departments [26, 27]. Recently, a

**Table 3. Comparison of selective testing criteria.**

Model	Women screened	Cases identified	Prevalence in screened women	Prevalence in unscreened women	Cases in black/NA women
STC-1	47	80	0.53	0.12	75.4
STC-2	52	89	0.54	0.07	100
STC-3	58	86	0.46	0.10	85.3

**NOTE.** Data are percentages. NA, Native American; STC-1, selective testing criteria 1 (risk factor based); STC-2, selective testing criteria 2 (race based; STC-1 plus individual race); STC-3, selective testing criteria 3 (geography based; STC-1 plus local geographic prevalence in men).

case-control study in California family-planning clinics found that testing all women <25 years old would detect 94% of cases while screening 56% of women [28]. On the basis of this, the California Department of Health Services recommends routine screening for women <25 years old in family-planning and primary care settings and risk factor–based screening for women >25 years old (a history of gonorrhea during the preceding 2 years, having >1 sex partner during the preceding year, having a nonmonogamous sex partner, and being a black woman 26–30 years old) [29]. Performance characteristics of these recently implemented criteria have not yet been evaluated. Our study population consisted primarily of women <25 years old who were already being tested for *C. trachomatis*. Thus, these criteria are most applicable to young women seeking chlamydia screening. Although it would be interesting to assess the performance of USPSTF guidelines for gonorrhea screening [9] in this population, IPP clinics do not routinely collect data on many of these criteria (e.g., previous gonococcal infection, inconsistent condom use, sex work, and drug use).

Implementing selective testing for gonorrhea may prove challenging. At present, most public health laboratories use multiplex assays that test for gonococcal and chlamydial infection simultaneously [10]. Testing for chlamydial infection alone would require a stand-alone assay for women who do not meet gonorrhea testing criteria. This could prove logistically difficult and would require clinicians to differentiate between women who meet 2 different sets of criteria. Such operational challenges, however, must be weighed against the potential benefits of cost savings and reducing false-positive test results.

Although detailed cost-effectiveness analyses are required to determine the magnitude of savings associated with selective testing strategies, rough estimates suggest that moderate savings could be obtained under existing pricing scenarios. At present, the Gen-Probe APTIMA CT assay costs ~80% of the combined APTIMA COMBO 2 assay (personal communication, Nate Richardson, Gen-Probe, San Diego, CA). Under the assumption of an annual volume of 60,000 tests at \$12 per multiplex assay, substituting a stand-alone assay for *C. trachomatis* in women not meeting the geography-based testing criteria (42%) would save >\$50,000. Implementing risk factor– or race-based criteria would further reduce the number of women tested, with greater cost savings. Although these savings are modest, they may be justified, given current difficulties in sustaining public funding for chlamydial testing. Moreover, if diagnostic test manufacturers adopted a larger price differential between stand-alone and combined tests, savings could be much larger.

In addition to reducing costs, selective testing could also diminish the risk of false-positive results in low-prevalence populations (<1%) [15]. Even highly specific assays may have unacceptably low positive predictive values in such settings. Although a validation study in Washington State (0.5% prev-

alence) found that only 3% of specimens positive for gonorrhea by APTIMA COMBO 2 assay were potentially falsely positive [14], false-positive *N. gonorrhoeae* test results have been a problem with the COBAS AMPLICOR CT/NG assay (Roche Molecular Systems), and confirmatory testing is required in low-prevalence populations [15, 30–32]. Adopting selective testing criteria could reduce the risk of false-positive results by increasing the prevalence of infection among those tested.

The strengths of our analysis include the large number of women from diverse locations in Washington State. However, women of nonwhite racial/ethnic groups were particularly underrepresented here, and this population may not be representative of other locations. Furthermore, only women who were screened for *C. trachomatis* are represented here. However, screening for *N. gonorrhoeae* is not recommended in the absence of screening for *C. trachomatis* [33], given the higher prevalence of the latter in most settings. Our findings are applicable to low-prevalence settings; selective testing criteria for gonorrhea in medium- and high-prevalence settings should also be explored.

Undetected gonococcal infections can ascend to the upper reproductive tract, causing PID, infertility, and ectopic pregnancy [18]. The importance of identifying and treating these infections must be balanced against the limited budget available to many public health programs with competing priorities and the potential for false-positive results in low-prevalence populations. Selective testing criteria for low-risk settings that are based on risk factors and incorporate either race or local area geographic prevalence provide a sensitive and reasonably specific alternative to the current practice of universally testing all women for gonorrhea when they are screened for chlamydial infection.

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