HHS Public Access

Author manuscript

Sex Health. Author manuscript; available in PMC 2019 December 05.

Published in final edited form as:

Sex Health. 2015 November ; 12(6): 512–519. doi:10.1071/SH15044.

How do changes in the population tested for chlamydia over time affect observed trends in chlamydia positivity? Analysis of routinely collected data from young women tested for chlamydia in family planning clinics in the Pacific Northwest (USA), between 2003 and 2010

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Abstract

Background: The proportion of chlamydia tests that are positive (positivity) is dependent on the population tested and the test technology used. The way in which changes in these variables might affect trends in positivity over time is investigated.

Methods: Data from 15- to 24-year-old women tested for chlamydia in family planning clinics participating in the Infertility Prevention Project in the Pacific Northwest, United States (USA Public Health Service Region X) during 2003–2010 (n = 590 557) were analysed. Trends in positivity and in test, demographic and sexual behaviour variables were identified. Unadjusted and adjusted trends in chlamydia positivity were calculated using logistic regression.

Results: The proportion of tests carried out using nucleic acid amplification tests (NAATs) increased dramatically during the analysis period in two states. Smaller changes in demographic and behavioural characteristics were seen. Controlling for test technology used had the largest effect on the trend in testing positive per year, leading to a fall in the calculated odds ratio of testing positive from 1.06 to 1.02 in Oregon, and from 1.07 to 1.02 in Idaho. Controlling for other variables had minimal effect on chlamydia positivity trends.

Conclusions: Changes in NAAT use had a large effect on observed trends in chlamydia positivity over time in the two states where NAATs were introduced during the analysis period. While trends in chlamydia positivity may be a useful metric for monitoring chlamydia burden, it is important to consider changes in test type when interpreting these data.

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Conflicts of interest

No conflicts of interest declared.

Introduction

During 1993–2011, the Infertility Prevention Project (IPP), a federally funded project to prevent infertility, supported increasing access to screening and treatment for *Chlamydia trachomatis* (chlamydia) and *Neisseria gonorrhoeae* (gonorrhoea) among young women attending family planning, sexually transmitted disease (STD) and other health clinics in the United States (US). Funding was provided to state and city health departments and to a regional infrastructure, which formed regional advisory committees composed of state STD programs, family planning and women's health programs and public health laboratories. Data on women tested for chlamydia were collected in clinics participating in the IPP and collated regionally. Data were used to supplement chlamydia case report data to monitor trends in chlamydia and for program evaluation and quality improvement activities at a clinic, state and regional level.[1]

Among 15- to 24-year-old women tested in family planning clinics participating in the IPP, the proportion of chlamydia tests that were positive (hereafter 'positivity') increased during 2000–2011.[1] However, this does not necessarily mean that the population prevalence of chlamydial infection (defined as the proportion of the general population who are infected with chlamydia) increased during this period. Positivity is dependent on the population tested and test technology used,[2–4] so does not equate directly to true population prevalence. Consequently, observed trends in chlamydia positivity may be due to changes in the characteristics of the population tested at different time points,[3] or changes in the type of diagnostic test used[1] rather than changes in the underlying burden of disease in the population. Interpreting observed trends without consideration of changes in the population tested over time could lead to erroneous conclusions about the changing burden of disease over time. Satterwhite *et al.* reported that, after accounting for changes in clinic attendee demographics (age, race, geography) and test technology, positivity among 15- to 24-year-old women tested in family planning clinics participating in the IPP between 2004 and 2008[5] remained stable, contrary to national trends in crude positivity. However, as limited information was available at the national level, they were unable to account for other, potentially important, changes in the population screened that could affect the positivity among those tested. For example, they did not account for changes in the proportion of tests conducted among symptomatic women or among those with a recent positive test.

Understanding what factors affect observed trends in positivity is critical to interpreting trends in existing IPP data, as well as for identifying the potential utility of different data items for use in future surveillance systems. In order to investigate the impact of changes in the population of clinic attendees on observed trends in chlamydia positivity, we analysed data from young women tested for chlamydia in family planning clinics that participated in the IPP in the United States' Pacific Northwest [US Public Health Service (USPHS) Region X], an area that collected enhanced data elements not available in most other USPHS regions. We aimed to identify to what extent changes in test, demographic or behavioural characteristics of clinic attendees tested for chlamydia between 2003 and 2010 might have affected the observed trends in positivity over the analysis period.

Methods

Data sources

We analysed IPP chlamydia test records from Region X (comprising the states of Washington, Idaho, Oregon and Alaska) female family planning clients aged 15–24 years, for the period 2003–2010. Equivocal test results were excluded.

Test-level data were collected and collated regionally. The following variables were available: (1) test result; (2) year of test; test technology [nucleic acid amplification test (NAAT) or non-NAAT]; (3) patient age in years; race/ethnicity (non-Hispanic white or other); (4) reported abnormal discharge; (5) reported exposure to chlamydia; having more than one sexual partner in the last 60 days; (6) having a new sexual partner in the last 60 days; and (7) reason for test (re-screen after positive test or other). A test was considered to be a re-screen if the patient reported the reason for visit as ‘re-screen’ or if they had a known chlamydia diagnosis in the previous 12 months (self-reported or identified in the IPP dataset).

Exploring the effect of changes in characteristics on the observed trends in positivity

We reported test, demographic and behavioural characteristics for tests over time, stratified by state. We used logistic regression to identify the trend in chlamydia positivity during 2003–2010. Year was included as a continuous variable, with test result (positive/negative) as the outcome variable. The annual percentage observed change in positivity was estimated using the odds ratio (OR) of testing positive for chlamydia per additional test year. A series of bivariable models were constructed that included test result as the outcome variable and year and one other variable as predictors (e.g. year and age, year and race/ethnicity, year and exposure to chlamydia). We compared the estimated annual observed change in positivity with the estimated change resulting from the different models in order to explore whether there was any evidence that changes in the available demographic and behavioural variables or in test technology had any effect on the observed trends in chlamydia positivity.

All variables were then included in a multivariable model to determine the combined effect on observed trends in positivity. In the multivariable model, having more than one sex partner in the previous 60 days and having a new sex partner in the previous 60 days were combined into a single measure (reporting either or both vs reporting neither) to avoid collinearity.

Sensitivity analysis to explore the potential impact of test technology on positivity trends

Inclusion of test type (NAAT/non-NAAT), as described above, indicates that the test type has a substantial impact on the observed trend in positivity. However, the model predictions of positivity would not reflect the true proportion of those tested who had an infection, as this would not fully account for sensitivity and specificity of tests used. We therefore carried out sensitivity analyses of data from Idaho and Oregon, where substantial changes in test technology occurred during the analysis period. A logistic regression model correcting for sensitivity and specificity of tests used was constructed for Idaho and Oregon data using the ‘logitem’ command in Stata.[6] Sensitivity and specificity estimates from a previous review of

chlamydia diagnostic tests[7] were applied for each of the tests, or package inserts for tests not included in the review.[8–10] In order to explore potential error in sensitivity and specificity estimates arising from imperfect gold standards for chlamydia testing,[11] alternative scenarios were modelled using combinations of the reported sensitivity 5 percentage points, and specificity ±1 percentage point for the main tests used during the period in each state (Probe and TC-TMA in Idaho; signal amplification and TC-TMA in Oregon). The resulting predicted positivities from logistic regression models were plotted against the observed data (Fig. 4).

All statistical analyses were performed using Stata version 12.0 (StataCorp, College Station, Texas, USA).

Results

A total of 590 557 tests among 15- to 24-year-old women were included. The median age was 20 years and 60% of tests came from women aged 20–24 years. The majority of tests were among women of non-Hispanic white race/ethnicity (71%). Washington and Oregon contributed the highest number of tests (45% and 36%, respectively). Overall, 6.1% of tests were positive. Nineteen per cent reported a new sexual partner in the last 60 days and 8.6% reported more than one sexual partner in the last 60 days (Table 1). During 2003–2010, the total number of tests per year conducted in Region X IPP family planning declined 20% from 78 352 (2003) to 62 755 (2010). The majority of this decline was due to a fall in tests reported in Washington State during 2003–2007 (Fig. 1).

Trends in reported characteristics of clinic attendees and the use of NAATs

Trends in the reported demographic and behavioural characteristics of those tested, and in the use of NAATs during the study period, varied by state. In Washington (Fig. 2a, b), the proportion of women tested who reported having either multiple sex partners or a new sex partner declined slightly from 2003 to 2006, and then increased slightly up to 2010. The proportion of tests among females of non-white, non-Hispanic race increased from 2003 to 2007, and then remained stable. Other characteristics remained relatively stable in this state. In Oregon (Fig. 2c, d), there was a steady decline in the proportion of tests among 15- to 19-year-olds, from 43% in 2003 to 30% in 2010. The proportion reporting abnormal discharge declined from 12% to 8%, but other variables remained stable. In Idaho (Fig. 2e, f), notable changes included a fall in the proportion of tests among 15- to 19-year-olds from 2003 to 2005, an increase in the proportion of tests where multiple or new partners in the previous 60 days were reported, and an increase in the proportion of tests among people of non-white, non-Hispanic race. Demographic and behavioural variables fluctuated more in Alaska (Fig. 2g, h), which was likely due to the smaller sample size from this state.

In Idaho and Oregon, the proportion of tests that were conducted using NAATs increased substantially from <6% in 2003–2004 to 99% from 2006 onward in Idaho (Fig. 2e), and from <1% between 2003 and 2008, to 100% in 2010 in Oregon (Fig. 2c). Washington and Alaska reported NAAT use in excess of 98% throughout the period (Fig. 2a, d).

Impact of changes in characteristics of clinic attendees and the use of NAATs on state-specific trends in positivity

Overall, chlamydia positivity was 6.1% and varied by state, ranging from 4.8% in Oregon to 8.6% in Alaska. An increase in the proportion testing positive (unadjusted for other factors) was observed in Idaho and Oregon, from 5.5% in 2003 to 7.2% in 2010 in Idaho (OR 1.07, 95%CI 1.05–1.08) and 4.2% to 6.4% in Oregon (OR 1.06, 95%CI 1.05–1.07) (Fig. 2). Observed positivity remained relatively stable in Washington during this period (OR 0.99, 95%CI 0.99–1.00), and no consistent trend was observed in Alaska (OR 1.01, 95%CI 0.99–1.03).

The adjusted ORs of testing positive per year are shown in Fig. 3. Adjusted ORs are reported where each demographic and behavioural variable was included with year in the bivariable models (indicated by black diamonds); for the multivariable analysis, all variables were included (indicated by red diamonds).

In both the bivariable and multivariable analyses, all variables were statistically significantly associated with testing positive (data not shown). In Oregon and Idaho, controlling for test technology had the largest effect on the odds of testing positive per year. In Oregon, a 6% annual increase in positivity was observed before adjustment, whereas after controlling for test technology, the annual estimated increase in positivity fell to 2% (AOR 1.02, 95%CI 1.01–1.03). In Idaho, the unadjusted trend showed a 7% annual increase, which decreased to a 2% annual increase after adjustment for test type (AOR 1.02, 95%CI 1.00–1.04). Negligible differences were seen between unadjusted and adjusted ORs of testing positive per year when variables other than test technology were included in the bivariable models.

In the multivariable model, adjustment made a substantial difference to the OR of testing positive per year in Idaho. The adjusted OR (indicated by the red diamond in Fig. 3) was 1.02, whereas the unadjusted OR (indicated by the open diamond in Fig. 3) was 1.07. Most of this difference was accounted for by controlling for test technology.

The ORs from multivariable models were more similar to the unadjusted ORs in Oregon (AOR 1.04, OR 1.06).

Sensitivity analysis to explore potential impact of test technology on positivity trends

Figure 4 shows the observed and model-predicted positivities for a range of scenarios, adjusting for estimated sensitivity and specificity of tests used in Idaho and Oregon. Applying the literature-derived point estimates resulted in a sensitivity- and specificity-adjusted OR of testing positive per year of 1.04 (95% CI 1.03–1.06) in Idaho (Fig. 4a) and 1.12 (95%CI 1.10–1.14) in Oregon (Fig. 4b). Depending on the combination of sensitivity and specificity estimates applied to the two main tests used during the period, the sensitivity- and specificity-adjusted OR ranged from 0.99 (95%CI 0.97–1.00) to 1.12 (95%CI 1.10–1.14) in Idaho and 1.04 (95%CI 1.02–1.05) to 1.30 (95%CI 1.27–1.32) in Oregon.

Discussion

Our analysis of data from young women tested for chlamydia in family planning clinics that participated in the IPP in the Pacific Northwest showed that changes in NAAT use over time had a substantial effect on the observed trends in positivity in the two states where NAATs were introduced during the analysis period. There was some variation in the reported demographic and behavioural characteristics of the women tested in family planning clinics as part of the IPP over time. However, the observed differences made relatively little difference to the observed trend in positivity.

By incorporating patient-level factors not available in the national IPP dataset, we could explore the impact of changes in demographics and reported sexual behaviour over time on observed trends in positivity. Our analyses were, however, limited to variables collected routinely. It is possible that the population changed in ways that were not captured by the available variables, either because some risk factors were not measured or because the categories available were not sufficiently detailed. For example, we categorised individuals according to whether they reported a new sexual partner in the last 60 days. We could not apply more precise categories that would have distinguished those who had one new partner from those who had many more. In Alaska and Washington (where NAATs were used across the period), the proportion of those tested who reported an abnormal discharge changed over time. This may indicate variations in testing practices in clinics, with increased/decreased testing among asymptomatic patients. It was not possible to investigate this further as data on variations in testing practices over time were not available. However, we note that chlamydia screening of young women was regularly stressed as part of semi-annual Region X IPP program meetings, which may have contributed to increases in testing among asymptomatic women. Positivity trends in Alaska closely followed patterns seen in the percentage reporting abnormal discharge, but in neither Washington or Alaska did adjusting for abnormal discharge have a notable effect on overall conclusions about trends in positivity over the period studied. A further limitation is that clinics that contributed data to the IPP varied over time. As such, trends in positivity may have varied if our analysis had been limited to a set of clinics that had consistently contributed data over the analysis period. However, as our analysis was designed to look at factors affecting trends in positivity, rather than the absolute trends in infection, we don’t consider this likely to have substantially affected our findings.

Increasing use of NAATs had the most effect on the observed trends in positivity. It is well documented that NAATs are considerably more sensitive than other available chlamydia tests, and that changes in test technology should be considered when calculating and interpreting trends in chlamydia positivity.[2,4] However, national reports of positivity trends have not been consistently adjusted for changes in NAAT use over time.[1] Our analysis adds to existing evidence demonstrating the importance of interpreting chlamydia positivity or case report trends in the context of changes in test type. Our sensitivity analyses of predicted positivity with varying test performance characteristics further demonstrates the potential impact of test technology, as the observed trend in positivity was dependent on the assumptions about sensitivity and specificity of the tests used. Further work is needed to fully understand the impact of assumptions on correction for test sensitivity and specificity.

We documented variation in trends by state within Region X. While it is possible that changes in the tested population affected trends in different states, it is also feasible that there were different underlying trends in population prevalence in these states. Unadjusted reports of positivity trends at a national or regional level may be of limited value for local public health planning, as these are likely to mask substantial variation between states or within states across counties, municipalities or family planning agencies.

The effect of changes in the population tested on observed positivity depends on the extent to which client characteristics are associated with positivity and the variation in characteristics over time. In our analysis, although the available demographic and behavioural variables were associated with testing positive, they did not vary enough over time to have a substantial impact on the measured positivity trend. This is consistent with a previous analysis of chlamydia positivity in Region X for the period 1997 to 2004.[12] In other states, clinical settings or time periods, the tested population might change more over time. For example, changes in selective screening protocols, the availability of clinical services in the area[3] or in the underlying risk behaviours of the eligible population may occur. More significant changes would likely have a greater impact on positivity trends. To illustrate this, we investigated two hypothetical scenarios. Using the distribution of reported characteristics observed in Region X in 2003 as a baseline, we estimated the positivity following a 5% or 10% annual increase in the number of women tested who had each characteristic (Fig. 5). For example, a relative increase of 5% per year in the proportion of the tested population reporting either multiple or new sexual partners in the last 60 days would lead to a 7% overall increase in observed positivity during 2003–2010 (rising from 6.0% to 6.4%) (Fig. 4). Similarly, a relative increase of 5% per year of the population tested who were aged 15–19 years old would result in a 5% overall increase in observed positivity (rising from 6.0% to 6.3%) (Fig. 5). These changes would be solely due to the selection effects of changes in the population tested (i.e. with no change in the population prevalence). The observed increase in positivity would, of course, be higher with greater changes in the characteristics of the population tested. This is important because many programs do not collect, or do not routinely use, data on demographic and behavioural risk factors, and may therefore overlook the impact of changes in either the risk profile of clinic attendees or in the population offered testing on trends in crude positivity.

Given the availability of information on numbers of tests and test results, women attending family planning services remain a useful sentinel population to indicate chlamydia burden in the US – albeit in a selected population – and trends in positivity may be a useful metric. However, as trends in chlamydia positivity are used to inform and evaluate chlamydia screening programs,[13–15] understanding the potential limitations of these data, and appreciating the context in which they are collected, is essential. In order to maximise the utility of surveillance data, patient-level demographic and behavioural data and information on test uptake and test technology within any clinical setting should be collected and incorporated into positivity analyses. As clinics have embraced electronic health record systems in recent years, monitoring client characteristics and risk factors may be more readily attainable. The choice of variables should be steered by the association between each factor and positivity, the likelihood of obtaining accurate measurement of each variable, the feasibility of data collection and program and policy goals.

Acknowledgements

The authors thank the patients and clinics who contributed data. This work was supported by funds from the Division of STD Prevention, Centers for Disease Control and Prevention, Atlanta, GA. At the time of the study, SW and KS worked for the Health Protection Agency (now part of Public Health England), who received funding from the Department of Health. The views expressed in this publication are those of the authors and not necessarily those of the Department of Health. The findings and conclusions in this report do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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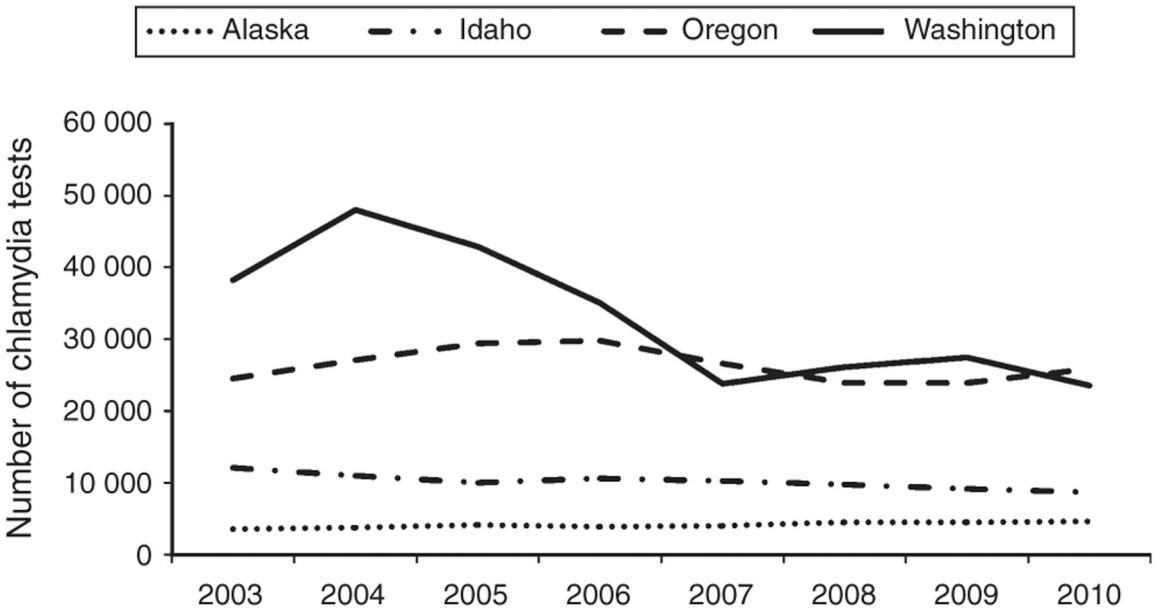

Fig. 1.

Number of chlamydia tests among women aged 15–24 years who were tested in family planning clinics in Region X and reported to the Infertility Prevention Project (2003–2010).

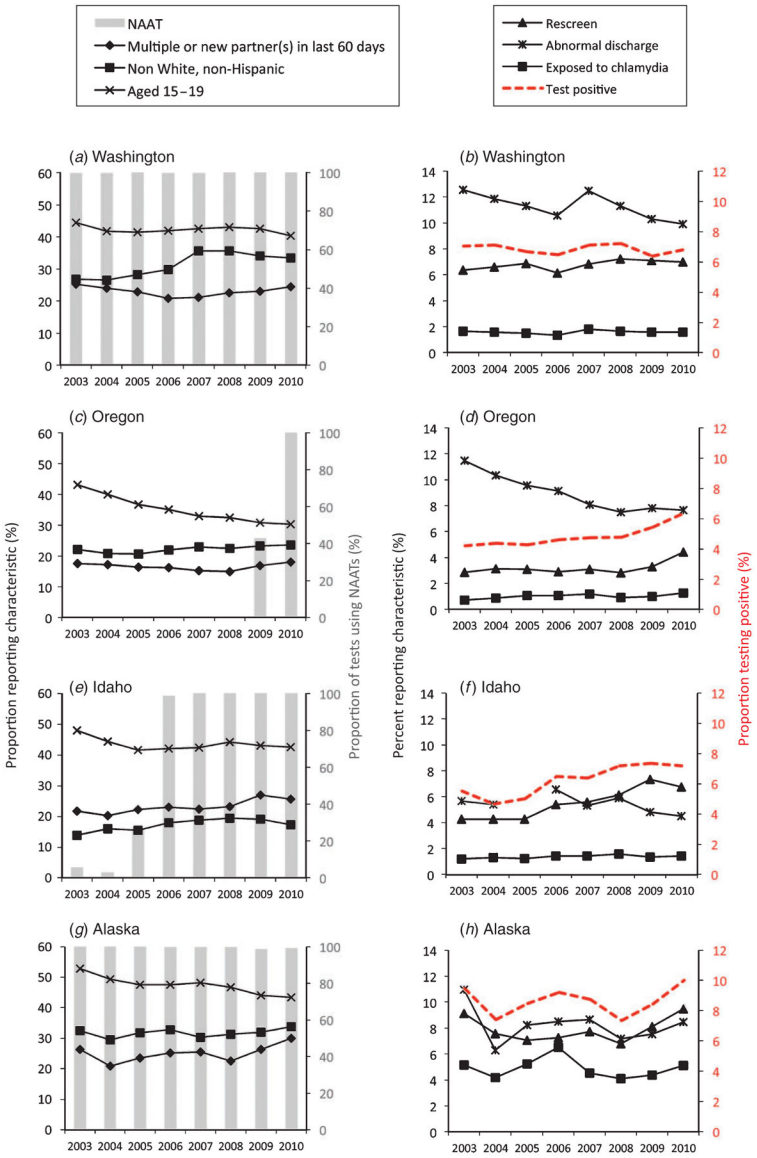

Fig. 2.

(*a–h*) Test, demographic and behavioural characteristics and chlamydia positivity among women aged 15–24 years tested for chlamydia in Region X family planning clinics reported to the Infertility Prevention Project (2003–2010).

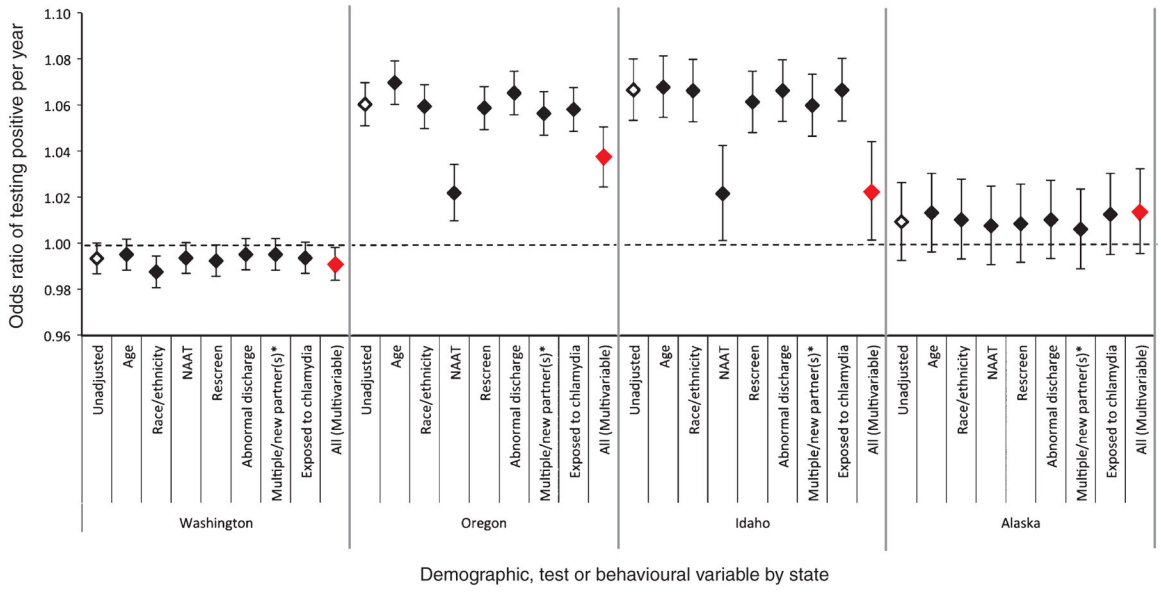

Fig. 3.

Unadjusted and adjusted (bivariable and multivariable) odds ratios of testing positive per year among women aged 15–24 years who were tested in family planning clinics in Region X and reported to the Infertility Prevention Project (2003–2010). *More than one and/or at least one new sexual partner in the previous 60 days. (◊), Unadjusted ORs; (✦) show results for models where year and the specified variable were included; Closed red diamonds (✦) show results for multivariable models where year and all other variables were included. Whiskers show 95% confidence interval.

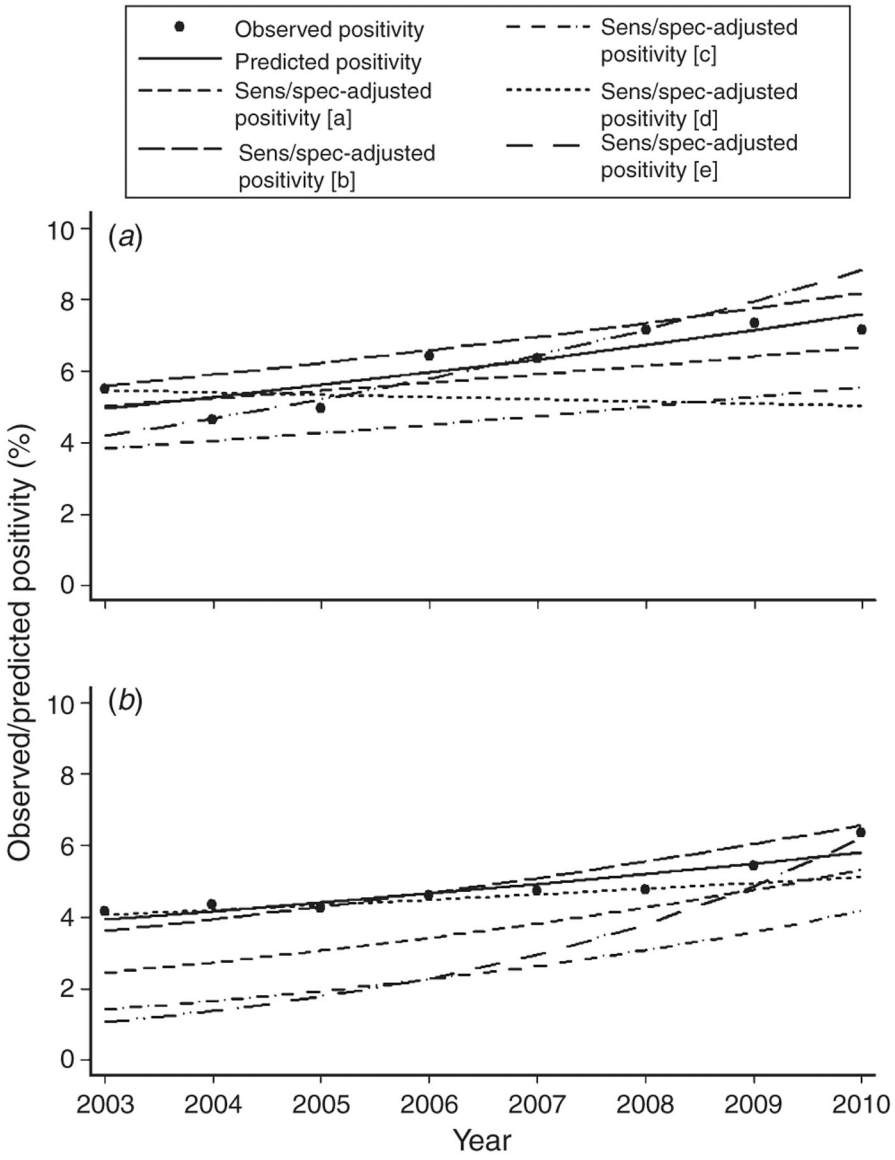

Fig. 4.

Observed and predicted positivity with and without adjustment for estimated sensitivity and specificity of diagnostic tests. (*a*) Idaho, (*b*) Oregon. (●) show the observed positivities in each year. Solid and dashed lines show positivities predicted from logistic regression models, with year entered as a continuous variable. The solid line presents predicted positivity without adjustment for sensitivity or specificity of the tests. Dashed lines present predicted positivities from sensitivity- and specificity-adjusted models, using estimates derived from the literature. Scenarios labelled [b] to [e] show model scenarios using combinations of the reported sensitivity ± 5 percentage points and specificity ±1 percentage point for the main tests used during the period in each state (in Idaho the Gen-Probe Aptima Combo 2 and Gen-Probe PACE 2 accounted for >99% of all tests. In Oregon the Gen-Probe Aptima Combo 2 and Digene, Hyprid capture 2 CT/GC test accounted for 92% of all tests). [a] Linear trend, sensitivity and specificity point estimates adjusted. [b] Minimum

sensitivity, maximum specificity for each test. [c] Maximum sensitivity, minimum specificity for each test. [d] Minimum sensitivity and maximum specificity applied to Gen-Probe PACE 2(Idaho)/Digene, Hyprid capture 2(Oregon); Maximum sensitivity and minimum specificity applied to Gen-Probe Aptima Combo 2. [e] Maximum sensitivity and minimum specificity applied to Gen-Probe PACE 2(Idaho)/Digene, Hyprid capture 2(Oregon); Minimum sensitivity and maximum specificity applied to Gen-Probe Aptima Combo 2.

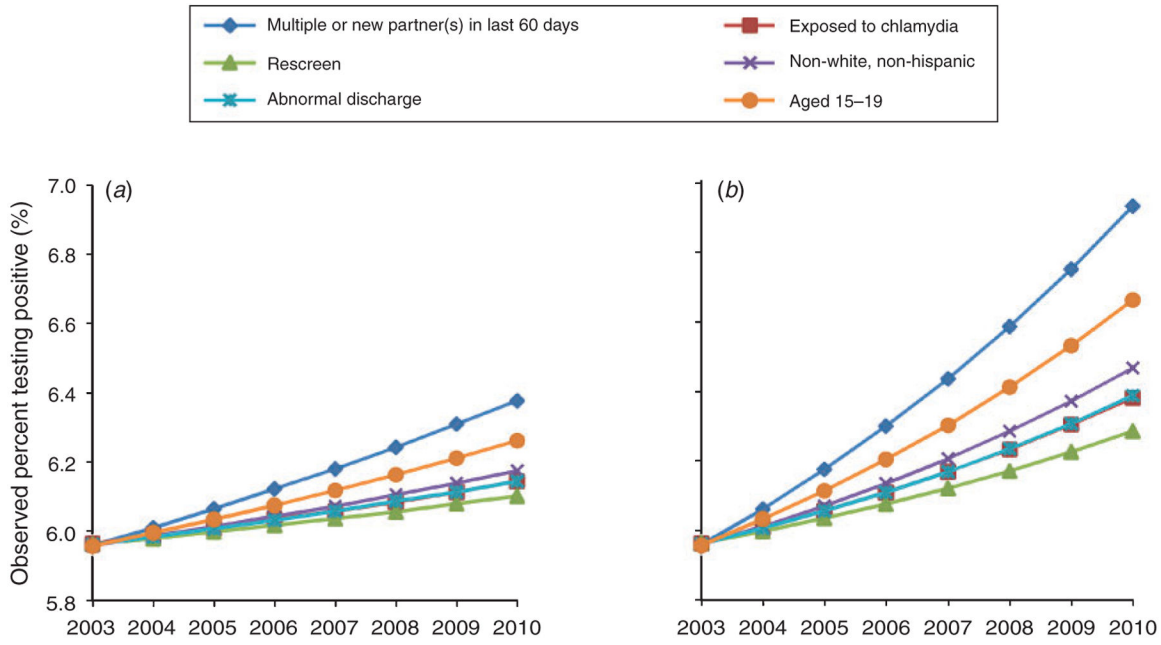

Fig. 5.

(*a*, *b*) Hypothetical scenarios regarding changes in observed proportion testing positive for chlamydia, given changes in the population tested, using 2003 Region X Infertility Prevention Project data from family planning clinics as baseline values. (a) Scenario 1, a 5% increase per year in proportion with each characteristic among the population tested. (b) Scenario 2, a 10% increase per year in proportion with each characteristic among the population tested.

Table 1.

Demographic, behavioural and test characteristics of 15- to 24-year-old women tested for chlamydia at family planning clinics participating in the Infertility Prevention Project in the Pacific Northwest region of the United States (2003–2010)

NAAT, nucleic acid amplification test

Characteristic	Number (N = 590 557)	Percentage
Test result		
Negative	554 457	93.9
Positive	36 100	6.1
Age group		
15–19 years	237 608	40.2
20–24 years	352 949	59.8
Race[A]		
White	472 154	80.0
Asian	22 561	3.8
American Indian/Alaskan Native	12 314	2.1
Black	29 078	4.9
Native Hawaiian/Pacific Islander	7166	1.2
Other	35 875	6.1
Unknown	27 375	4.6
Race/ethnicity		
White, non-Hispanic	420 920	71.3
Other	145 266	24.6
Unknown	24 371	4.1
State		
Alaska	32 974	5.6
Idaho	81 187	13.7
Oregon	211 184	35.8
Washington	265 212	44.9
Test type		
NAAT	385 940	65.4
non-NAAT	204 083	34.6

Characteristic	Number (N = 590 557)	Percentage
Unknown	534	0.1
More than one sexual partner in the last 60 days		
Yes	50 567	8.6
No	518 850	87.9
Unknown	21 140	3.6
At least one new sexual partner in the last 60 days		
Yes	112 257	19.0
No	457 356	77.4
Unknown	20 944	3.5

[A] More than one race can be chosen, therefore total adds up to >100%.

Table 2.

Percent reporting specified characteristics in 2003 and after hypothetical annual 5% or 10% increase in reported characteristic

Values are presented as percentages

	Baseline value in 2003[A]	Hypothetical value in 2010	
		After 5% increase per year	After 10% increase per year
Multiple/new partner(s) in last 60 days	22.3	31.4	43.5
Exposed to chlamydia	1.4	2.0	2.8
Re-screen	5.0	7.1	9.8
Non-White, non-Hispanic	23.4	33.0	45.6
Abnormal discharge	11.3	15.9	22.0
Aged 15–19 years old	44.9	63.2	87.5

[A] Baseline values in 2003 are derived from the overall proportions of tests reporting these characteristics in Region X in 2003.