RAPID DIAGNOSTICS

Evaluation of a rapid point-of-care test for the detection of gonococcal infection among female sex workers in Benin

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Objectives: To assess the validity of the PATH (Seattle, Washington, USA) GC-Check rapid test, a point-of-care immunochromatographic strip test, in the detection of gonococcal infection among female sex workers (FSWs) in Benin.

Methods: Women consulting consecutively at two FSW-dedicated clinics in Cotonou and Porto Novo (Benin) were recruited over three, 1-month periods between October 2003 and July 2004. After written informed consent, participants were administered a short interview and underwent a speculum examination where two cervical swabs were collected (in a subset of women, a vaginal swab was also collected). One cervical swab and the vaginal swab were immediately tested with the rapid test. The other cervical swab was frozen at −20°C for at most four weeks and then transported to Québec (Canada), where it was tested with the Roche Amplicor CT/NG PCR assay. Samples positive for gonococcal infection were confirmed using a 16SrRNA PCR assay.

Results: 1084 FSWs (median age 29 years) participated in the study, of whom 50 (4.6%) had a confirmed gonococcal infection. The sensitivity, specificity, positive and negative predictive values of the rapid test on cervical samples were 70.0% (95% confidence interval (CI) 55.4% to 82.1%), 97.2% (95% CI 96.0% to 98.1%), 54.7% and 98.5%, respectively. The sensitivity of the rapid test on vaginal swabs among 759 women (37 positives for gonococcal infection) was significantly lower than with the cervical swab (54.1%, p = 0.008), whereas the specificity was comparable (98.2%, p = 0.13).

Conclusions: The PATH GC-Check test may be as efficient as a gold standard polymerase chain reaction (PCR) test for treating gonococcal infection when taking into account the proportion of women who do not return for their test results. In clinics serving populations with moderate prevalence of this infection, it could significantly reduce over-treatment compared to the syndromic approach.

The diagnosis of genital gonococcal infections among women in low income countries remains a major challenge.[1] Despite the availability of many tests to detect this infection, most require laboratory facilities, are costly, and their results are not usually available before the patient has left the clinic. Several studies, in both developing[2] and developed[3] countries, have shown that patients often fail to return for their results and that the use of rapid point-of-care (POC) diagnostic tests with lower sensitivity than reference standard tests could lead to the treatment of a larger number of infected subjects than when such treatment is provided at the return visit.

In resource limited settings, the World Health Organization (WHO) recommends the use of the syndromic approach for the management of bacterial sexually transmitted infections (STIs) in both men and women. Syndromic management generally works well in men. However, several studies have shown that syndromic management of women with the common complaint of vaginal discharge is neither sensitive nor specific in identifying women who have an STI.[4 5] It is not sensitive because most women with STIs have no symptoms.[6] It is not specific because most women with vaginal discharge are not suffering from a cervical infection but rather from a derangement of the normal vaginal bacterial flora, such as bacterial vaginosis or vulvo-vaginal candidiasis. Although the application of a modified syndromic approach allowing for clinical screening of asymptomatic infections have led to improved STI control among high-risk women, such as female sex workers (FSWs),[7] the low sensitivities and specificities of all clinical approaches for diagnosing gonococcal infection result in many false diagnoses, massive over-treatment, and many STIs remaining untreated.

There is thus clearly a need to develop and evaluate rapid POC tests for the diagnosis of cervical infections by *Neisseria gonorrhoeae*. Our team has been involved in a project supporting FSW clinics in Benin since 1993; despite a massive decline in the prevalence of *N gonorrhoeae*, whose prevalence was 43% in 1993, a study carried out in 2002 still showed a prevalence of gonococcal infection of about 15%. This situation provided the opportunity to evaluate new rapid POC tests for gonococcal infection. Consequently, we joined the programme to evaluate simple rapid tests for different STIs initiated by the Sexually Transmitted Diseases Diagnostics Initiative (SDI) at WHO.

The objective of this study was to evaluate the validity of the PATH GC-check rapid test (Program for Appropriate Technology in Health, Seattle, Washington, USA), a POC immunochromatographic strip test, in the detection of gonococcal infection among FSWs in Benin.

METHODS

Study population and recruitment of participants

Women consulting consecutively (mostly for monthly routine examination) at two FSW-dedicated clinics—in Cotonou, the largest city and economic capital of Benin (Dispensaire IST (DIST), a clinic with long standing experience in clinical research), and Porto-Novo, the political capital of Benin (Clinique Solidarité-Sidaction (CSS), a clinic participating for

Abbreviations: CHA, Centre hospitalier *affilié* universitaire de Québec; CSS, Clinique Solidarité-Sidaction; DIST, Dispensaire IST; FSW, female sex worker; OD, optical density; PATH, Program for Appropriate Technology in Health; PCR, polymerase chain reaction; SDI, Sexually Transmitted Diseases Diagnostics Initiative; STI, sexually transmitted infection; WHO, World Health Organization

the first time in a clinical study)—were recruited over three, 1 month periods in 2003–2004 (October-November 2003; February–March 2004; June–July 2004). The only exclusion criteria were: being aged <18 years; having their periods on the day of consultation; having already participated in the study within the same one-month period; and having taken antibiotics in the three weeks preceding the study.

Study procedures

After written informed consent, participants were administered a short interview and underwent a speculum examination where two cervical swabs were collected (in a subset of women, a vaginal swab was also collected). The samples were collected by two medical doctors at DIST and by a nurse at CSS. One cervical swab and the vaginal swab were immediately tested with the rapid test and the results interpreted by two independent readers (a laboratory technician and a midwife at DIST; a laboratory technician and a medical doctor at CSS). The other cervical swab was frozen at –20°C for at most four weeks and transported to Québec (Canada), where it was tested at the STI laboratory of the Centre hospitalier *affilié* universitaire (CHA) de Québec by polymerase chain reaction (PCR). Participating women were treated free of charge for cervicitis, with a treatment for both *N gonorrhoeae* (ciprofloxacin 500 mg, single dose) and *Chlamydia trachomatis* (doxycycline 100 mg twice daily ×7 days), according to the clinical screening algorithm used in the participating FSW clinics.[8] In addition, the PCR testing in Canada was carried within a week of reception of the samples and the results were communicated to the treating physicians. Women were informed when results were available and had the opportunity to come to the clinic where aetiological treatment was provided free of charge to infected women who had not been diagnosed with clinical cervicitis at their previous visit. This study was approved by the ethics committee of the CHA (Québec) and by the Ministry of Health of Benin.

Rapid test

The PATH GC-check test was carried out according to the manufacturer's instructions: the swab was first immersed into a buffer contained in a flexible extraction tube, where it was agitated for 5 s and then allowed to stand for a minimum of 5 min and a maximum of 10 min. Then the walls of the tube were rolled between the thumb and forefinger for at least 30 s. After thoroughly squeezing the swab to extract any remaining liquid, a filter cap was pressed into the extraction tube opening and the swabs were then discarded appropriately. Finally, 2–4 drops of the extract were transferred from the extraction tube to the sample port marked S on the test cassette.

After 20 min, the results were read in a well lighted area by two independent readers: if a line appeared under the mark C (for control), the test was valid and its result was negative; if two lines appeared, one under C and one under T (for test), the result was positive; finally, if no control line was visible, the test was considered as invalid.

Reference standard tests

The samples sent to the CHA were first tested using the Roche Amplicor CT/NG PCR Assay (Roche Diagnostics Systems, Branchburg, New Jersey, USA). All samples with an optical density (OD) ⩾0.2 for *N gonorrhoeae* were retested in duplicate. All samples meeting the positivity criteria as per the manufacturer's instructions (that is, at least two tests with OD >0.2) were confirmed with a 16SrRNA PCR assay, using real time PCR technology (Light Cycler, Roche Diagnostics Systems, Inc) at a laboratory designated by Roche Diagnostics in Montréal, Canada. The reference standard for *N gonorrhoeae* positivity was defined as a positive NG Amplicor and a positive 16SrRNA PCR assay test.

Statistical analysis

The prevalence of gonococcal infection is reported with 95% confidence intervals (CI) for: (1) the reference standard; (2) a positive NG Amplicor according to the manufacturer's instructions; (3) a positive NG Amplicor result according to a more stringent criterion of having at least two out of three tests with ODs >2.0°; and (4) according to the rapid test on both cervical and vaginal swabs. We also report the prevalence of *C trachomatis* according to the result of the Amplicor test as per the manufacturer's instructions, the prevalence of infection by either *N gonorrhoeae* or *C trachomatis*, and the prevalence of cervicitis (leading to the treatment of both infections) according to the clinical screening algorithm currently in use among FSWs in Benin.

The sensitivity and specificity of the different assays as compared to our reference standard are presented with exact 95% CI based on the binomial distribution. We also present positive and negative predictive values, but without 95% CI because these measures are entirely dependent on the prevalence of disease in the study population given a fixed sensitivity and specificity.

As the inter-reader agreement for the results of the rapid tests were extremely high (99.7% for the rapid test on cervical swabs and 99.9% for rapid test on vaginal swabs), we considered the result of the rapid test as positive when at least one of the readers reported it as positive.

Finally, to compare the sensitivity and the specificity of the rapid test on cervical and vaginal samples, we used the McNemar χ^2 test for matched data, whereas for comparison of independent proportions, we used the Fisher's exact test.

RESULTS

A total of 1133 subjects were recruited over three, 1-month collection periods, of whom 49 (4.3%) were excluded for missing values on either the cervical swab rapid test or the reference standard test, for a resulting sample size of 1084 for the main analysis, including 876 recruited at DIST (Cotonou) and 208 at CSS (Porto Novo). As vaginal swabs were not collected in the second round of data collection, results from only 759 such swabs (616 from DIST and 143 from CSS) were available for analysis. Finally, sufficient clinical data were available to assess the outcome of the clinical screening algorithm for the diagnosis of cervicitis among 998 subjects.

Median age of the participants was 29 years. The vast majority of them consulted for regular monthly check-ups (89.6%), whereas 5.4% consulted for STI symptoms and 5.0% for non-STI related complaints.

The prevalence of *N gonorrhoeae* was 4.6% according to the reference standard (table 1). Among the 81 cervical samples positive by the NG Amplicor, 31 were not confirmed by the 16SrRNA PCR assay, resulting in a specificity of 97.0% (95% CI 85.8% to 98.0%) for the NG Amplicor. There were only nine less false positive results when applying the more stringent criterion for NG Amplicor positivity (at least two tests out of three with OD >2.0), resulting in a specificity of 97.9% (95% CI 96.8% to 98.7%). With a prevalence of 4.7% for *C trachomatis* and the presence of eight dual infections, there was a total of 93 women (8.6%) with either gonococcal of chlamydial infection. Finally, nearly 20% of the participants were diagnosed with clinical cervicitis.

The sensitivity of the PATH GC-check rapid test carried out on cervical swabs was 70.0% whereas its specificity was 97.2%, resulting in positive and negative predictive values of 54.7% and 98.5%, respectively (table 2). The sensitivity of the rapid test on

Table 1 Prevalence of genital chlamydial and gonococcal (according to different diagnostic criteria) infections and clinical cervicitis among FSWs in Benin, 2003–04

Diagnostic criterion	n	Number positive	% positive (95% CI)
NG-positive (reference standard*)	1084	50	4.6 (3.4 to 6.0)
NG-positive (Amplicor – manufacturer's instructions)	1084	81	7.5 (6.0 to 9.2)
NG-positive (Amplicor–stringent criterion†)	1084	72	6.6 (5.2 to 8.3)
NG-positive (rapid test – cervical swab)	1084	64	5.9 (4.6 to 7.5)
NG-positive (rapid test – vaginal swab)	759	33	4.4 (3.0 to 6.1)
CT-positive (reference standard)	1084	51	4.7 (3.5 to 6.2)
NG and/or CT-positive (reference standard)	1084	93	8.6 (7.0 to 10.4)
Cervicitis according to clinical algorithm‡	998	199	19.9 (17.5 to 22.6)

CI, confidence interval; CT, *C trachomatis*; NG, *N gonorrhoeae*.
*Positive by both NG-Amplicor (manufacturer's instructions) and the 16SrRNA PCR.
†At least two out of three Amplicor tests with OD>2.0 for NG.[9]
‡The clinical diagnosis of cervicitis leads to treatment of both NG and CT.

vaginal swabs (54.1%) was, however, significantly lower ($p = 0.008$, McNemar χ^2 test), whereas the specificities on both types of samples were comparable ($p = 0.13$, McNemar χ^2 test). The sensitivity of the rapid test on cervical swabs was significantly lower in Porto Novo than in Cotonou (38.5% *v* 81.1%, $p = 0.011$, Fisher's exact test). Whereas the sensitivity was stable at DIST (Cotonou) during the three rounds of the data collection (between 80–82%), it increased significantly ($p = 0.021$, Fisher's exact test) between the first two rounds (0/6 = 0%) and the last round (5/7: 71.4%) at CSS (Porto Novo).

The results of the clinical screening algorithm were available for 86 of the 93 subjects infected by either *N gonorrhoeae* or *C trachomatis* according to the reference standard, and for 912 of the 991 subjects without any of these infections. Of these 86 infected subjects, only 33 (38.4%, 95% CI 28.1% to 49.5%) were diagnosed with cervicitis, whereas there were 166 subjects without gonococcal or chlamydial infection among the non-infected subjects, for a specificity of 81.8% (95% CI 79.1% to 84.2%) of the clinical screening algorithm. The latter had positive and negative predictive values of 16.6% (33/199) and 93.4% (746/799), respectively.

DISCUSSION

The prevalence of gonococcal infection was much lower than previously estimated using similar PCR testing in this population, confirming a significant impact of the FSW intervention in both cities.[7] However, this lower prevalence reduced the scope of this evaluation, with only 50 cases of cervical infection by *N gonorrhoeae* according to the gold standard, whereas about 100 cases were initially expected when we planned the study.

In comparison with our reference standard, the sensitivity of the PATH GC-check rapid test on cervical swabs was higher than what was previously reported for microscopic examination of Gram-stained smears prepared from cervical swabs[10]—the only POC test ever thoroughly evaluated for the diagnosis of cervical gonococcal infection among women before the launch of the SDI evaluations. Furthermore, the sensitivity of the PATH GC-check test on vaginal swabs was comparable to that reported for cervical Gram-stained smears (50%). The specificity we found for the rapid test on both vaginal and cervical swabs is comparable to that reported for the latter diagnostic procedure in women.[10] Finally, the PATH GC-check test has the important advantage of being technically much easier to carry out than examination of Gram-stained smears and does not require microscopy, which makes it much more suitable for use at the primary health care level in developing countries.

When taking into account previous data showing that only about 50% of FSWs consulting at the DIST come back for a return visit within 10–15 days,[2] using the results of the reference standard test on cervical swabs for treating the infected women would have resulted in treatment of only about 25 subjects out of the 50 with gonococcal infection, compared to 35 who would have immediately been treated based on the rapid test result.

The sensitivity of the rapid test was lower at CSS (Porto-Novo), a clinic with less research experience than DIST (Cotonou) and where a nurse took the clinical samples, compared to a physician at DIST. However, with experience, the sensitivity of the test improved at CSS, suggesting that the sensitivity of the PATH GC-check rapid test could in fact be higher than 70% when used by experienced health care workers (sensitivity was 81% at DIST and stable over time).

Some previous data suggest that the confirmatory assay used in this study (16SrRNA PCR assay) could lack sensitivity, especially when the detection method following amplification is based on an enzyme immunoassay (EIA),[11] which would result in an overestimation of the sensitivity of the PATH GC-check rapid test. However, some recent data suggest that this

Table 2 Performance of the PATH GC-Check rapid test in the diagnosis of gonococcal infection among female sex workers in Benin compared to a reference standard of positive Amplicor PCR for *N gonorrhoeae* confirmed by a 16SrRNA PCR according to type of sample and city of recruitment, 2003–04

	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	PPV (%)	NPV (%)
For the 2 cities combined				
Cervical swab (n = 1084)	35/50 (70.0) (55.4 to 82.1)	1005/1014 (97.2) (96.0 to 98.1)	35/64 (54.7)	1005/1020 (98.5)
Vaginal swab (n = 759)	20/37 (54.1) (36.9 to 70.5)	709/722 (98.2) (96.9 to 99.0)	20/35 (60.6)	709/726 (97.7)
For Porto-Novo				
Cervical swab (n = 208)	5/13 (38.5) (13.9 to 68.4)	187/195 (95.9) (92.1 to 98.2)	5/13 (38.5)	187/195 (95.9)
Vaginal swab (n = 143)	3/10 (30.0) (6.7 to 65.2)	130/133 (97.8) (93.5 to 99.5)	3/6 (50.0)	130/137 (94.9)
For Cotonou				
Cervical swab (n = 876)	30/37 (81.1) (64.8 to 92.0)	818/839 (97.5) (96.2 to 98.4)	30/51 (58.8)	818/825 (99.1)
Vaginal swab (n = 616)	17/27 (62.9) (42.4 to 80.6)	579/589 (98.3) (96.9 to 99.2)	17/27 (62.9)	579/589 (98.3)

CI, confidence interval; NPV, negative predictive value; PPV, positive predictive value.

confirmatory assay is in fact highly sensitive, especially when using a real time PCR methodology,[12] as in this study. The use of a confirmatory assay following a positive Amplicor test for *N gonorrhoeae* is in any event warranted, given the specificity problems of the NG Amplicor, as previously reported.[13–15] Nevertheless, there is still a possibility that our results overestimate the sensitivity of the PATH GC-check test because recent studies of second generation nucleic acid amplification tests, such as Transcription Mediated Amplification, suggest that the sensitivity of the NG/CT Amplicor PCR assay is suboptimal.[16 17] However, this problem is potentially more important on alternative clinical specimens, such as urine, than when using cervical swabs.

We chose to present results on the validity of the clinical screening algorithm currently used for the diagnosis of cervical infections among FSWs in Benin for the purpose of general comparisons of diagnostic approaches in developing countries. Indeed, despite a small decrease in sensitivity but an increase in specificity compared to previous studies where we evaluated this approach,[2 8] the positive predictive value has dramatically decreased over time (around 17% in this study compared to over 50% in 1993 and 38% in 1999) because of a massive decrease in the prevalence of STIs, especially that of *N gonorrhoeae*.[7]

Thus, even among high-risk women, such as FSWs, the low specificity of syndromic management (or of clinical screening algorithms which are an adaptation of the latter for high-risk women) may result in over-treatment on a massive scale. For lower risk women, in addition to the cost and possible side effects resulting from over-treatment, the over-diagnosis of STIs may carry an important personal and social cost, especially when women are encouraged to refer their husband and other sexual partners for treatment.[18–20] However, in very low prevalence settings like in most developed countries, the current specificity of the rapid test may still lead to a low positive predictive value and thus, unacceptable over-treatment.

In conclusion, the PATH GC-check rapid test may be at least as efficient as a gold standard test for treating *N gonorrhoeae* when taking into account the proportion of women who do not return for their test results,[21] especially when using cervical samples. In clinics serving populations with moderate prevalence of *N gonorrhoeae* and where speculum examination is possible, it could significantly reduce over-treatment compared to the syndromic approach or to the application of clinical screening algorithms in populations such as FSWs. Finally cost-effectiveness studies are needed to compare the use of such tests with that of the syndromic and other clinical approaches in both high-risk and low-risk women.

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AUTHOR CONTRIBUTIONS

MA was the principal investigator of the study, carried out the general supervision of the data collection and analysis and wrote the manuscript. CGA carried out the field data collection at DIST and contributed to the data analysis. GA carried the field data collection at DIST, supervised the data collection at CSS and carried out the rapid test at CSS. MND was a co-investigator on the study, contributed to the training of all study staff and coordinated all the field work. ACL was a co-investigator on the study, contributed to the training of the study staff and supervised the laboratory work in Canada. DF carried out the PCR assays in Canada. MS contributed to the study design and to the training of the study staff. RWP was heading the research programme for the evaluation of rapid STI tests at SDI, WHO, and contributed to the training of the study staff. All the authors contributed to the study design and protocol. They also revised and approved the manuscript.

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