RAPID DIAGNOSTICS

Clinic-based evaluation of Clearview Chlamydia MF for detection of *Chlamydia trachomatis* in vaginal and cervical specimens from women at high risk in China

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Sex Transm Infect 2006;**82**(Suppl V):v33–v37. doi: 10.1136/sti.2006.022475

Objectives: To determine the performance of a rapid *Chlamydia trachomatis* (CT) test (Clearview Chlamydia MF) compared to the current "gold standard" (Roche Amplicor CT assay) test, and to assess acceptability of the tests to patients.

Methods: A total of 1497 women at sexually transmitted diseases (STD) clinics or re-education centres in six urban cities (Shanghai, Nanjing, Shenzhen, Guangzhou, Chengdu and Fuzhou) in China participated in the study. Three vaginal and three cervical swabs were collected from each participant. Rapid CT tests were performed locally on the first vaginal and cervical swabs and the results were read independently by two staff members. The second and third swabs were randomised for performing the Roche CT assay at the National STD Reference Laboratory. Acceptability of the rapid tests to patients was determined by asking patients in clinics about their willingness to wait for the results.

Results: The prevalence of CT was 13.2% (197/1497), as determined by the Roche assay with cervical specimens. CT was detected in 78 vaginal and 127 cervical specimens by the rapid test and the positive rates determined with cervical specimens were significantly higher than those with vaginal specimens ($p < 0.001$). There was good agreement between the results read by two independent staff for either vaginal or cervical specimens (both $\kappa = 0.98$, $p < 0.001$). Sensitivities for vaginal and cervical specimens were 32.8% and 49.7%, respectively, and specificities were 99.2% and 97.9%, respectively. The positive predictive value was 85.7% for vaginal and 78.4% for cervical specimens. The vast majority of the patients (99.1%) were willing to wait up to two hours for the results.

Conclusion: Clearview Chlamydia MF, while yielding a rapid result and requiring minimal laboratory facilities, had unacceptably low sensitivity compared to a nucleic acid amplification test. Rapid tests yielding results within one hour are generally accepted by the clients.

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Accepted 6 November 2006

The pathogen *Chlamydia trachomatis* is an important sexually transmitted disease. Besides causing urethritis and cervicitis, this infection, if undiagnosed and untreated, may result in serious secondary complications and sequelae including pelvic inflammatory disease (PID), ectopic pregnancy and infertility.^{1–3} In addition, *C trachomatis* infection increases the risk of HIV transmission and acquisition,⁴ and may be a cofactor in the development of cervical cancer.⁵ The World Health Organization (WHO) estimated that 92 million new *C trachomatis* infections occurred in 1999.⁶ In China, chlamydial infection is not reported as a separate notifiable sexually transmitted disease (STD),^{7, 8} but a rapid increase of reported cases of non-gonococcal urethritis and cervicitis (NGU), of which the majority is believed to be caused by *C trachomatis*, has been observed in the National STD Surveillance System.⁹ Moreover, recent ad hoc prevalence surveys among different populations in China have revealed a high burden of chlamydial infections.^{10, 11}

Since individuals, particularly women, infected with *C trachomatis* are often asymptomatic,¹² symptom-based case detection is unreliable for case management or surveillance. Laboratory-based diagnosis of chlamydial infections has been gradually introduced into clinical services and surveillance practice in the country. Culture was traditionally used for the laboratory diagnosis of chlamydial infections in China. However, culture was not widely available as it is expensive, and required technical expertise and a cell culture facility. In

the early 1990s, antigen detection assays which were easier to perform and less expensive than culture became available. In particular, results of evaluations of the Clearview Chlamydia MF Test showed that it had sensitivities of 80–95% and specificities of 98–99.9% against culture or a combined reference standard of culture and laboratory-based enzyme immunoassays^{13–19} (table 1). It was approved for use in China and became widely used as it requires a short time (<30 min) from sampling to obtaining a result, and does not require specialised equipment or extensive training. Patients can be treated at the same clinic visit and partner notification can be initiated.

With the introduction of nucleic acid amplification tests (NAATs), such as the polymerase chain reaction (PCR), into China, there is the potential to further improve the sensitivity of detection of genital chlamydial infections.^{20, 21} However, their substantially higher costs, strict requirements for specialised laboratory personnel and facilities, as well as the concerns on quality control, led the government to restrict use of NAATs for clinical diagnosis to certified laboratories only. Although two studies comparing Clearview Chlamydia MF with nucleic acid

Abbreviations: FRCs, female re-education centres; NAAT, nucleic acid amplification test; NGU, non-gonococcal urethritis; NPV, negative predictive value; PCR, polymerase chain reaction; PID, pelvic inflammatory disease; PPV, positive predictive value; SEVs, sex entertainment venues; STD, sexually transmitted disease; STDCs, STD clinics; WHO, World Health Organization

Table 1 Published studies reporting the performance of the Clearview Test

Study population	No.	Sex	Prevalence (%)	Reference standard	Sensitivity (%)	Specificity (%)	Reference
Department of genitourinary medicine clinic	375	F	17.5	Culture + immunofluorescence (MicroTrak)	93.5	99	Arumainayagam <i>et al</i> , 1990 (UK) ¹⁶
Gynaecology clinic, hospital	965	F	4.8	Culture + antigen detection EIA	80.4	99.9	Skulnick <i>et al</i> , 1991 (Canada) ¹⁴
Gynaecology clinic, medical centre	648	F	6.2	Culture	95	98	Stratton <i>et al</i> , 1991 (USA) ¹⁵
Genitourinary medicine unit, hospital	478	F	8.8	Culture + immunofluorescence	85.7	99.1	Young <i>et al</i> , 1991 (UK) ¹³
Student health clinic, family planning and prenatal clinic	506	F	9.3	Culture + immunofluorescence	85.1	98.5	Ferris <i>et al</i> , 1992 (USA) ¹⁷
Sexually transmitted infections clinic	724	F	7.5	Culture + PCR	62.3	99.7	Kluytmans <i>et al</i> , 1993 (Netherlands) ¹⁸
Outpatient obstetrics-gynaecology clinic	283	M	16.3	Culture, LCR, TMA, PACE-2, Clearview Any 3 of 4 tests +	60.4	86.3	Lauderdale <i>et al</i> , 1999 (USA) ¹⁹
	787	F	8.4		50	100	

amplification tests have reported sensitivities ranging from 50–62% and specificities ranging from 86–100%,^{18–19} there is an urgent need for validation of these data in the developing world to provide evidence for a change in policy. In the present study, we used the PCR assay as a reference standard to validate the performance of the Clearview Chlamydia MF among the women in different risk settings in China.

METHODS

Study population

The study was conducted among symptomatic or asymptomatic women at risk of infection with *C. trachomatis* who were recruited from STD clinics (STDCs), female re-education centres (FRCs) and sex entertainment venues (SEVs) in six sites (Chengdu, Fuzhou, Nanjing, Shanghai, Guangzhou and Shenzhen). Women who had used antibiotics in the previous three weeks were excluded. A total of 1500 eligible subjects agreed to participate in the study, but 1497 (839 from STDCs, 587 from FRCs and 71 from SEVs) were included in the study because three subjects did not provide specimens. Information on demographic characteristics was obtained with structured questionnaires by trained clinic staff. The study was approved by the WHO research ethics review committee and the medical ethics committee of the National Center for STD Control. Informed consent was obtained from each subject before the interview and specimen collection. Women were asked whether they would be prepared to wait for up to two hours for their test results.

Specimen collection and testing

Three vaginal swab and three cervical swab specimens were collected from each participant. The three vaginal swabs were collected simultaneously with sterile Dacron-tipped plastic swabs (Unipath Ltd, Bedford, UK) before the collection of the three cervical swab specimens in order to avoid contamination of the vaginal canal with cervical discharge. One vaginal swab specimen and the first cervical swab specimen were used for testing with Clearview Chlamydia MF (Clearview, Unipath Ltd, Bedford, UK) at the local laboratories the same day as specimens were collected in accordance with manufacturer's instructions. The remaining dry swabs were refrigerated at –20°C at the local laboratory temporarily before being transported to the National STD Reference Laboratory in Nanjing for further testing with Amplicor PCR assay (Roche, Branchburg, New Jersey, USA). The testing with Clearview was performed by one technician at each local laboratory, but the test results were read independently by two staff members in order to assess reproducibility in the interpretation of results. One each of the remaining vaginal and cervical swabs was used

to test for *C. trachomatis* with Amplicor PCR assay, according to manufacturer's instructions, using a thermocycler (GeneAmp 9700, Perkin-Elmer, Norwalk, Connecticut, USA).

Statistical analysis

Data were entered into a computer to establish a database using the Epi Info 6 Software (Centers for Disease Control and Prevention, Atlanta, Georgia, USA). Using the PCR result as a gold standard, a relative sensitivity and specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated. Statistical analysis of the data was also performed using the χ^2 test. A *p* value <0.05 was considered to be statistically significant. Kappa (κ) value was calculated for agreement between two readers or two test results. The agreement was classified, using the guidelines proposed by Landis and Koch,²² as marginal agreement (κ <0.4), good agreement ($0.4 \leq \kappa \leq 0.75$), and excellent agreement (κ >0.75). SPSS for Windows 11.0 (SPSS Inc, Chicago, Illinois, USA) and MedCalc for Windows 8.1 (MedCalc Software, Mariakerke, Belgium) were used to analyse the data.

RESULTS

The median age of the 1497 participants was 28 years; 587 participants (39.2%) were recruited from FRCs, 839 (56.0%) from STDCs, and 71 (4.7%) from SEVs. Out of 1497 women, 61.5% acknowledged symptoms including genital discharge. Using the criteria that positive test results by PCR assay with cervical specimens were classified as "infected", the prevalence of *C. trachomatis* infection was 10.7%, 13.8% and 25.4% among women from FRCs, STDCs and SEVs, respectively.

The results of the detection of *C. trachomatis* in women recruited from different settings using Clearview compared with those obtained by Roche PCR are shown in table 2. By using PCR test with the specimens from the anatomically corresponding site for calculation of the performance of the Clearview, the overall relative sensitivities of vaginal and cervical specimens were 32.8% (66/201) and 49.7% (98/197); specificities 99.2% (1285/1296) and 97.9% (1273/1300); PPVs 85.7% (66/77) and 78.4% (98/125); and NPVs 90.5% (1285/1420) and 92.8% (1273/1372), respectively. There were statistically significant differences in the overall sensitivities, specificities and NPVs between vaginal and cervical specimens in terms of their use in the Clearview test, indicating that cervical swab specimens had a significantly higher sensitivity ($\chi^2 = 11.06$, *p* = 0.001) and higher NPV ($\chi^2 = 4.48$, *p* = 0.03). The significant difference in sensitivity was observed among women from either FRCs or STDCs. There was no statistically significant difference in sensitivities between women recruited from different settings, but the specificity among women from

Table 2 Performance of the Clearview with PCR test in detection of *C trachomatis* infection by recruitment setting and specimen type†

Source and type of specimens	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	PPV (%) (95% CI)	NPV (%) (95% CI)
FRC (n = 587)				
Vaginal swab	24.2* (14.9 to 36.6)	99.4 (98.2 to 99.9)	84.2 (59.5 to 95.8)	91.2 (88.5 to 93.3)
Cervical swab	44.4 (32.1 to 57.4)	99.4 (98.2 to 99.9)	90.3 (73.1 to 97.5)	93.7 (91.3 to 95.5)
STDC (n = 839)				
Vaginal swab	36.8* (28.2 to 46.2)	98.9 (97.7 to 99.5)	84.3 (70.9 to 92.5)	90.6 (88.3 to 92.5)
Cervical swab	52.6 (43.1 to 61.9)	96.7 (95.0 to 97.8)	71.8 (60.8 to 80.7)	92.7 (90.6 to 94.4)
SEV (n = 71)				
Vaginal swab	38.9 (18.3 to 63.9)	100.0 (91.6 to 100)	100.0 (56.1 to 100)	82.8 (70.9 to 90.7)
Cervical swab	50.0 (26.8 to 73.2)	100.0 (91.6 to 100)	100.0 (62.9 to 100)	85.5 (73.7 to 92.7)
Total (n = 1497)				
Vaginal swab	32.8** (26.5 to 39.9)	99.2 (98.4 to 99.6)	85.7 (75.5 to 92.3)	90.5* (88.8 to 91.9)
Cervical swab	49.7 (42.6 to 56.9)	97.9 (96.9 to 98.6)	78.4 (70.0 to 85.1)	92.8 (91.3 to 94.1)

*p<0.05 and **p<0.01, the p values (χ^2 test) refer to the differences between different swab specimens in terms of recruitment settings.

†Performance as compared to PCR test using the corresponding specimens.

CI, confidence interval; FRC, female re-education centre; NPV, negative predictive value; PCR, polymerase chain reaction; PPV, positive predictive value; STDC, sexually transmitted diseases clinic; SEV, sex entertainment venue.

FRCs (99.4%) was significantly higher than that among patients from STDCs (96.7%; $\chi^2 = 9.56$, $p = 0.002$). PPVs for cervical swabs were different among women recruited from different settings, showing the lowest PPV in women attending STD clinics ($\chi^2 = 7.29$, $p = 0.03$).

The relationship between genital discharge and the performance of the Clearview is shown in table 3. The sensitivity, specificity, PPV or NPV was not significantly associated with the symptoms of vaginal discharge. However, having cervical discharge was significantly associated with a higher sensitivity and lower specificity.

There were excellent agreements between the results read by two independent staff for either vaginal or cervical specimens in different study sites (κ statistics ranged 0.94 to 1.00 for tests with vaginal specimens and 0.96 to 1.00 for cervical specimens; all p values were <0.001).

A qualitative assessment of the suitability and acceptability of rapid tests for use in primary health care settings was assessed by the 14 staff members who performed the rapid tests after they completed the first 50 rapid tests. Many technicians recognised that the kit provided a very clear manufacturer's instruction (92.9%); the test had a 10-min hands-on time (85.7%), and was fairly or very easy to use (85.7%) and rapid (<20 min) to display results (100%); the result was fairly or very easy to interpret (100%); and the training of operational

procedures took ≤ 30 min (92.9%). Regarding the acceptability of rapid diagnostics to patients, the vast majority of the patients (99.1%) were willing to wait up to two hours for the results, among whom 83.1% preferred to waiting for 30 min.

DISCUSSION

The Clearview Chlamydia MF has been commercially available for many years and is widely used in clinical settings, particularly in STD clinics in urban areas in China. In recent years, commercial NAAT assays such as Roche Amplicor CT PCR kit have been introduced into the country, but the applications of these assays in clinical services are limited by the restricted laboratory requirements and high cost compared with conventional immunoassays for antigen detection.

Cell culture for *C trachomatis* has previously been the reference standard.^{15–17} Currently, the accepted standard to validate the assays for detection of *C trachomatis* is an NAAT.¹⁹ The sensitivity of the Clearview Chlamydia MF (49.7%) reported in the present study is comparable to that of Clearview EIA with endocervical swabs (50%),¹⁹ indicating a poor sensitivity. A low PPV (78.4%) due to the large number of false-positive results is also a concern and it is related to the possible cross-reactivity of the Clearview Chlamydia MF with other bacteria in reproductive tracts. This is in part supported by our findings that PPVs were lower in patients with symptoms of vaginal or cervical discharge when the PCR with cervical swab specimens was used as the standard. The difference in PPVs among women recruited from different settings is mainly due to their difference in prevalence of chlamydial infection.²³

The sensitivity of the Clearview Chlamydia MF in this study is less (93.8%, 60/64) than that among females reported in the manufacturer's package insert. The difference in the sensitivity (49.7%) reported in our study is most likely due to the comparison of the Clearview Chlamydia MF with an amplification assay. The studies used to calculate the test performance reported in the manufacturer's package insert were performed in comparison with the conventional cell culture.

Tests for *C trachomatis* infection may be used for screening asymptomatic women, or for guiding the clinical management of those with symptoms. In China, the Clearview test is widely used both for screening—for example, in re-education centres—and for clinical management of women presenting with vaginal discharge. As in many other studies, the prevalence of *C trachomatis* in this study population was no higher in those with than in those without symptoms. Study in China has

Table 3 Performance of the Clearview with PCR test in detection of *C trachomatis* infection by symptom of anatomical site

Symptom	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Vaginal discharge				
Yes (n = 921)	36.6	99.2	88.2	91.0
No (n = 576)	26.9	99.0	80.8	89.6
Cervical discharge†				
Yes (n = 537)	62.0**	96.5	75.4	93.6
No (n = 960)	41.5	98.7	81.7	92.3
Vaginal discharge‡				
Yes (n = 921)	53.3	97.0	72.7*	93.3
No (n = 576)	44.2	99.4	91.9	92.0

*p<0.05 and **p<0.01, the p values (χ^2 test) refer to the differences between having and not having discharge symptoms in terms of anatomical sites of the discharge.

†Performance as compared to PCR test using the corresponding specimens.

‡Performance as compared to PCR test using cervical specimens.

NPV, negative predictive value; PCR, polymerase chain reaction; PPV, positive predictive value.

indicated that the specificity of treatment for chlamydial and gonococcal infections based on presence of vaginal discharge was less than 50%.²⁴ If the treatment is given to all women complaining of vaginal discharge for *C trachomatis* it would result in very substantial (more than 50%) over-treatment; hence the need for a diagnostic test. However, the sensitivity of Clearview MF was unacceptably low (<50%) in both women with and without symptoms. In this case, more than 50% of chlamydial infections would fail to be detected among the screening population, particularly in those without any symptoms, resulting in the delay of timely treatment of the infected persons and notification of their partners, and the further transmission of infections to sexual partners, particularly for those female sex workers who usually have several clients per week or even per night. For patients attending at the study clinics, treatment of chlamydial infection was based on the results of the Clearview test, which has been approved for China. PCR results were not used to guide the treatment because PCR testing currently remains largely a research tool in China, and in this study it was done at the National STD Reference Laboratory months later.

Sensitivities of vaginal swab specimens were universally lower than those with cervical swab specimens in the different populations, although the difference was not statistically significant, probably because of the small sample size. *C trachomatis* bacterial loads are higher in the endocervix than the vagina, but vaginal swabs do not require a speculum examination and can be self-administered. The presence of vaginal discharge did not significantly increase the sensitivity in our study.

Although the evaluation was conducted by technicians from seven laboratories of local STD clinics, most of these laboratories had experienced laboratory staff and good laboratory facilities. Thus, the results of this study may not reflect the performance characteristics of the test in the community- or clinic-based settings for which they are designed and where non-experienced laboratory or even non-laboratory staff is performing the assay. Real-world use of the rapid test in other areas or other clinical or community settings may not yield the same sensitivity reported here.

Several limitations of this study should be acknowledged. In our study, indeterminate results of Clearview Chlamydia MF were simply considered as negative results and the sensitivity may be increased by using other assays. The evaluation was conducted among women at high risk with a prevalence of *C trachomatis* of 10–25%. However, the performance of the evaluated test might be different if the test is validated in the population outside this prevalence range.

In summary, this prospective study showed that the Clearview Chlamydia MF, while yielding a rapid result and requiring minimal laboratory facilities, had a relatively low sensitivity in the study populations for diagnosing chlamydial infection as compared with PCR-based assay, which warrants careful consideration for use of this assay for the clinical diagnosis of *C trachomatis*. However, this assay is generally not technically complex to perform and is well accepted by the technicians and the clients. In settings where the prevalence of *C trachomatis* is high and/or the NAAT assay in terms of its specialised facilities and experienced staff is not available, the Clearview Chlamydia MF could be still considered a patient's point-of-care screening device and should be a useful addition to the bench-top assays currently available. It is able to detect those with high bacterial loads, who may be the most likely to develop sequelae or infect their sexual partners. However, our results might not be applicable to lower prevalence populations, such as those seen in family planning clinics, because the carriage of *C trachomatis* will be lower. Further studies are

required to justify the true usefulness and cost-effectiveness of rapid tests in clinical services and community-based interventions.

In the China National STD Surveillance Guidelines, chlamydial infections have been extracted from the list of traditional NGU STDs and are considered a separate STD for reporting. A policy on recommendations of an appropriate laboratory test for *C trachomatis* is urgently needed in China. In this country, where no laboratory services are available, patients presenting with vaginal discharge are treated for both chlamydia and gonorrhoea, resulting in >50% over treatment for these infections. In many STD clinics, however, chlamydial diagnosis and treatment services are routinely based on the identification of infections through the Clearview test, followed by treatment based on positive test results. Based on the results of this evaluation, it is now apparent that this results in failure to treat approximately 50% of those who are truly infected. Hence, the current approach is not optimal and a more sensitive point-of-care test is urgently needed both for screening and to support the clinical management of women presenting with symptoms.

ACKNOWLEDGEMENTS

The authors thank the staff of the collaborating facilities in Nanjing, Shanghai, Guangzhou, Fuzhou, Chengdu and Shenzhen where this study took place, whose collaboration was very much appreciated. The authors also thank all participants of this study for their wonderful cooperation. The study was supported by the financial assistance from UNICEF/UNDP/World Bank/WHO Special Programme for Research & Training in Tropical Diseases (TDR) (contract ID: OD/TS-05-00524).

CONTRIBUTORS

YPY and XSC were principal investigators who were responsible for the study design, data analysis, and manuscript preparation. RWP and DM were responsible for revision of the manuscript in addition to study design. KLG, HZ, WMG, HPZ, ZSW, GY and WLC were collaborators in study sites. MQS and XQD were the laboratory-based technicians who were responsible for the laboratory testing. WHW, QC and XG were responsible for field coordination and data management.

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Conflict of interest statement: Clearview Chlamydia MF test kits were provided by Unipath Ltd in the UK via the WHO/TDR Programme on Sexually Transmitted Diseases Diagnostics Initiative (SDI)

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