

# Evaluation of simple diagnostic algorithms for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* cervical infections in female sex workers in Abidjan, Côte d'Ivoire

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**Objective:** To generate simple algorithms for the diagnosis of cervical infection with *Neisseria gonorrhoeae* or *Chlamydia trachomatis* in female sex workers in Abidjan, Côte d'Ivoire and to evaluate their validity.

**Methods:** From October 1992 to the end of June 1993, female sex workers were interviewed and clinically examined at a confidential clinic. *N gonorrhoeae* was cultured on modified Thayer-Martin medium and *C trachomatis* was detected by polymerase chain reaction. The associations of gonococcal or chlamydial cervical infection with sociodemographic, behavioural, clinical, and biological factors were assessed and three algorithms were generated. The validity parameters of these diagnostic algorithms were calculated and compared to those of standard algorithms and mass treatment.

**Results:** Among 683 women, cervical infection was present in 239 (35%). The sensitivity of an algorithm incorporating sociodemographic and behavioural factors and symptoms, of an algorithm incorporating clinical signs and simple laboratory tests, and of a combined algorithm was 83%, 86%, and 79% respectively while the specificity was 32%, 44%, and 54%, and the positive predictive value 40%, 46%, and 48% respectively. A standard algorithm incorporating only the symptom vaginal discharge, and a standard algorithm requiring both the symptom vaginal discharge and the presence of an endocervical mucopurulent discharge on examination had a sensitivity of 44% and 18%, a specificity of 75% and 95%, and a positive predictive value of 49% and 67% respectively.

**Conclusions:** The algorithms generated in this study may be useful for the control of cervical infections in female sex workers in resource poor settings in the absence of rapid, inexpensive, and accurate laboratory tests for the diagnosis of cervical infections.

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Keywords: diagnostic algorithms; *Neisseria gonorrhoeae*; *Chlamydia trachomatis*; female sex workers; Côte d'Ivoire

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## Introduction

Both ulcerative and non-ulcerative sexually transmitted diseases (STD) have been identified as factors facilitating sexual HIV transmission<sup>1-3</sup> and the control of STD is believed to be important in reducing the incidence of HIV infection.<sup>4</sup> The relative risk of genital ulcers for the transmission of HIV may be greater than that of cervical infection with *Neisseria gonorrhoeae* or *Chlamydia trachomatis*, but the population attributable risk of these cervical infections may be greater because of their higher prevalence.<sup>5</sup> Cervical infections with *N gonorrhoeae* or *C trachomatis* are very common among female sex workers in sub-Saharan Africa<sup>6,7</sup> and it is critical to control these often asymptomatic infections in these populations.

The detection of *N gonorrhoeae* and *C trachomatis* requires sophisticated laboratory techniques<sup>8</sup> that are usually not available in developing countries. Moreover, the results of these tests are not immediately available and treatment strategies based on these tests therefore require a return visit for the prescription of the appropriate treatment. The World Health

Organisation (WHO) has therefore proposed algorithms for the syndromic management of STD, including infections with *N gonorrhoeae* and *C trachomatis*, that are not dependent on sophisticated laboratory techniques,<sup>9</sup> but these algorithms are intended for use in patients consulting with STD related symptoms.

The objectives of this study were to generate simple and valid algorithms for the diagnosis of cervical infection with *N gonorrhoeae* or *C trachomatis* in both symptomatic and asymptomatic female sex workers reporting to a STD/HIV clinic; to compare the validity parameters of these generated algorithms with those of modified WHO proposed algorithms and mass treatment; and to simulate the positive predictive value and the proportion of women treated if these algorithms and mass treatment were to be applied in a similar population with a lower prevalence rate of cervical infection.

## Methods

### DATA COLLECTION

A cross sectional study was conducted from October 1992 to the end of June 1993 at a

confidential clinic for female sex workers in Abidjan, Côte d'Ivoire.<sup>7,10</sup> Briefly, female sex workers were invited to the clinic for free STD screening and treatment, HIV counselling and testing, and condom distribution. Following informed consent, a standard questionnaire was administered on sociodemographic and behavioural factors and on urogenital symptoms. A gynaecological examination, including abdominal palpation, a speculum examination, and a bimanual palpation, was performed by a physician. Cervical friability was defined as either frank bleeding from the cervical os or the observation of a bloody endocervical swab following the taking of three endocervical swabs. Endocervical swab specimens were obtained for the detection of *N gonorrhoeae* and *C trachomatis*. *N gonorrhoeae* was cultured on modified Thayer–Martin medium incubated in a candle extinction jar at 36°C for 24–48 hours.<sup>8</sup> Isolates were identified on the basis of typical colony morphology, oxidase reaction, and Gram stain result. Detection of *C trachomatis* on an endocervical sample was done by polymerase chain reaction (PCR) (Amplicor, Roche Diagnostic Systems, Branchburg, NJ, USA) and positive samples were retested by a PCR for the major outer membrane protein gene.<sup>11</sup>

Vaginal secretions were collected with a standard swab, which was immersed in a standard volume of 300 µl of saline and expressed on a slide for microscopic white blood cells (WBC) count. WBC were also counted in a smear of endocervical secretions. Results were reported as <10 or ≥10 WBC per high power field.

#### DATA ANALYSIS

The associations between various factors and cervical infection with *N gonorrhoeae* or *C trachomatis* were evaluated by the odds ratio and its 95% confidence interval by parametric or exact methods as appropriate, using the SPSS statistical package. Only women for whom data were available on all factors and who had results for both culture for *N gonorrhoeae* and PCR for *C trachomatis* were considered in this analysis. All evaluated factors were classified into risk markers and symptoms including socio-demographic and behavioural factors, and prompted reported symptoms and clinical signs and microscopy including clinical signs and WBC counts on vaginal and cervical secretions.

Three diagnostic algorithms were then generated based on factors that were significantly associated with cervical infection with *N gonorrhoeae* or *C trachomatis*. Algorithm A was generated for a situation where a clinical examination could not be performed and is based on a risk score incorporating significantly associated risk markers and symptoms. The presence of a significantly associated factor with an odds ratio of between 1 and 2 was given 1 point, while the presence of a significantly associated factor with an odds ratio of between 2 and 3 was given 2 points. In algorithm A women with a low risk score were considered non-infected, and women with a high risk score were considered infected. The cut off point was chosen

so that the sensitivity was at least 70% and the sum of sensitivity and specificity was maximal. Algorithm B was generated based on clinical signs and microscopy for a situation in which all participants would benefit from a speculum examination. Clinical signs and results of WBC counts were included in this algorithm if they remained significantly associated in a logistic regression model with forward selection ( $p < 0.05$ , Wald's test) of the variables that were significantly ( $p < 0.05$ ) associated with cervical infection in the univariate analysis. Finally, algorithm C was generated, aimed at reducing the proportion of women who would require an examination according to algorithm B. In algorithm C women with a low risk score were considered non-infected without being examined, women with a high risk score were considered infected without being examined, and women with an intermediate risk score were considered as possibly infected and would therefore be examined, applying algorithm B. The two cut off points were chosen so that the sensitivity was at least 70% and the sum of sensitivity and specificity was maximal.

The validity of algorithms was evaluated by calculating their sensitivity, specificity, and positive predictive value compared with the gold standard diagnosis of cervical infection. The number of women who would have been examined and treated if the algorithms were used for patient management was also calculated. This evaluation was performed for the three generated algorithms, for two modified WHO proposed algorithms, and for mass treatment. Since the WHO proposed algorithms are for use in symptomatic women,<sup>9</sup> asymptomatic women are considered non-infected in algorithms D and E for situations where a speculum examination is either not done (algorithm D) or done (algorithm E).

The positive predictive value and the proportion of women who would be treated according to the five algorithms and mass treatment was also simulated for a theoretical population of female sex workers with a prevalence rate of cervical infection of 10%, using the observed levels of sensitivity and specificity.

#### Results

A total of 683 women were included in this analysis. Their median age was 30 years (range 13–70); 89% were immigrants and only 48% had formal schooling. Their median duration of sex work was 3 years, the median price charged for intercourse was 500 FCFA (about \$1.5) and the median number of clients during their last working day was four. *N gonorrhoeae* and *C trachomatis* were detected in 31% and 11% of the women respectively, and cervical infection with either organism was present in 35%.

The associations of cervical infection with risk markers, symptoms, signs, and direct microscopy results in the univariate analysis are shown in table 1. The risk markers and symptoms that were significantly associated with cervical infection were being less than 20 years of age, having done sex work for 2 years

Table 1 Association of cervical infection with *N gonorrhoeae* or *C trachomatis* with risk markers, symptoms, clinical signs, and direct microscopy in female sex workers in Abidjan

	Cervical infection (n=239)		OR (95% CI)
	No (%)	No (%)	
<b>Risk markers and symptoms:</b>			
Age <20 years	32 (13)	26 (6)	2.5 (1.4-4.3)
Duration of sex work ≤2 years	124 (52)	175 (39)	1.7 (1.2-2.3)
Price for intercourse ≤500 FCFA	166 (70)	272 (61)	1.4 (1.0-2.0)
Number of clients ≥4	143 (60)	230 (52)	1.4 (1.0-1.9)
No other occupation	194 (81)	338 (76)	1.4 (0.9-2.0)
Ever sex during menses	100 (42)	153 (35)	1.4 (1.0-1.9)
Condom use <100%	204 (85)	361 (81)	1.3 (0.9-2.1)
No school education	123 (52)	205 (46)	1.2 (0.9-1.7)
Immigrant	214 (90)	394 (89)	1.1 (0.7-1.8)
Oral contraceptive	9 (4)	15 (3)	1.1 (0.5-2.6)
Vaginal discharge	106 (44)	111 (25)	2.4 (1.7-3.3)
Dysuria	77 (32)	90 (20)	1.9 (1.3-2.7)
Lower abdominal pain	118 (49)	207 (47)	1.1 (0.8-1.5)
Dyspareunia	94 (39)	165 (37)	1.1 (0.8-1.5)
Vulvar itching	93 (39)	183 (41)	0.9 (0.7-1.3)
Low back ache	121 (51)	259 (58)	0.7 (0.5-1.0)
<b>Clinical signs and microscopy:</b>			
Endocervical mucopus	89 (37)	49 (11)	4.8 (3.2-7.1)
Vaginal discharge	132 (55)	157 (35)	2.3 (1.6-3.1)
Friability	107 (45)	120 (27)	2.2 (1.6-3.0)
Cervical motion tenderness	54 (23)	70 (16)	1.6 (1.0-2.3)
Adnexal tenderness	27 (11)	33 (7)	1.6 (0.9-2.7)
Tender fossa iliaca	10 (4)	12 (3)	1.6 (0.7-3.7)
Cervical WBC ≥10/HPF	114 (48)	86 (19)	3.8 (2.7-5.4)
Vaginal WBC ≥10/HPF	143 (60)	132 (30)	3.5 (2.5-4.9)

FCFA=francs CFA; for most of the study duration \$1=300 FCFA; HPF=high power field.

Table 2 Validity of data generated and modified WHO recommended simple algorithms for the diagnosis of cervical infection with *N gonorrhoeae* or *C trachomatis*

Algorithm‡	Prevalence of cervical infection: 35%				Prevalence of cervical infection: 10%*		
	Sens† (%)	Spec† (%)	PPV† (%)	% Examined	% Treated	PPV† (%)	% Treated
A	83	32	40	0	73	12	70
B	86	44	46	100	66	15	59
C	79	54	48	44	57	16	49
D	44	75	49	0	32	16	27
E	18	95	67	32	9	29	6
Mass treatment	100	0	35	0	100	10	100

\* Results of a simulation considering a theoretical population of female sex workers with a prevalence rate of cervical infection of 10%, using the observed levels of sensitivity and specificity. † Sens=sensitivity; Spec=specificity; PPV=positive predictive value.

‡ See Results and figure 1 for a description of the algorithms. Algorithms A-C were generated from the data (see Methods section). Algorithms D and E are modifications of WHO proposed algorithms for use in symptomatic women. Mass treatment means treatment for all women without examination.

or less, having received 500 FCFA or less for their most recent sexual act, having had four or more clients during their most recent working day, having ever had sex during their menstrual period, reporting a vaginal discharge, and reporting dysuria. Among the clinical signs and microscopy the presence of a vaginal discharge, cervical motion tenderness, endocervical mucopus, a WBC count of ≥10 per high power field in both vaginal and cervical smears, and friability were all significantly associated; however, in a logistic regression model the presence of a vaginal discharge and of cervical motion tenderness were no longer significantly associated.

Figure 1 shows the three algorithms that were generated from the data (A-C) and the two modified WHO algorithms (D, E).<sup>9</sup> For algorithms A and C, a risk score was computed in which reported vaginal discharge and being less than 20 years old each scored two points; while having done sex work for 2 years or less, having received 500 FCFA or less for their most recent sexual act, having had four or more clients during their most recent working day, and reporting dysuria each scored 1 point (the

variable "ever sex during menses" was not included, since it considers a lifetime experience). In algorithm A women with a score of 0 or 1 were considered non-infected while women with a score of 2 or more were considered infected. In algorithm B women who presented with endocervical mucopus, cervical friability, or ≥10 WBC per high power field in either the vaginal or the cervical smear were considered infected. In algorithm C women with a risk score of 0 or 1 were considered non-infected, women with a risk score of 4 or more were considered infected, and women with an intermediate risk score of 2 or 3 were considered infected if they presented with endocervical mucopus, cervical friability, or ≥10 WBC per high power field in either the vaginal or the cervical smear. In the modified WHO proposed algorithms women who reported a vaginal discharge were considered infected in algorithm D and women who reported a vaginal discharge and presented endocervical mucopus were considered infected in algorithm E.

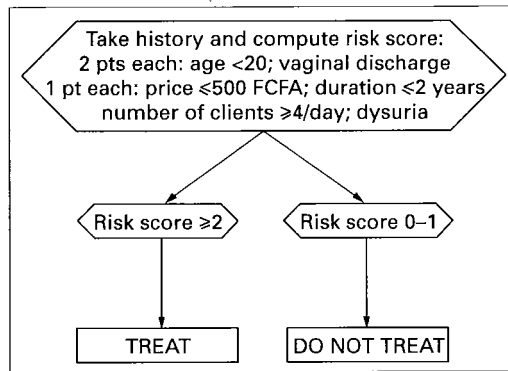
For the various algorithms shown in figure 1 and for mass treatment table 2 lists the parameters of validity including sensitivity, specificity, positive predictive value, as well as the number of women who would have been examined and treated when applying the respective algorithms. The sensitivities of 83%, 86%, and 79% of the generated algorithms A-C were much higher than the 44% and 18% sensitivities of the modified WHO proposed algorithms D and E, while the specificities of 32%, 44%, and 54% of algorithms A-C were much lower than the 75% and 95% specificities of algorithms D and E. The positive predictive values of algorithms A-D were very similar. Compared with algorithm B, algorithm C required examination of 44% of women instead of 100%. Algorithm E had the lowest sensitivity and highest specificity of all algorithms that were evaluated, resulting in a small proportion of women to be treated. For the mass treatment strategy, none of the women would be examined and all women would be treated.

Table 2 also lists the simulated positive predictive value as well as the simulated number of women who would have been treated when applying the respective algorithms and the mass treatment strategy for a theoretical population of sex workers with a prevalence of cervical infection of 10%. While the mass treatment strategy would still treat 100% of the women, the positive predictive value decreased to 10% for a prevalence of 10% compared with 35% for a prevalence of 35%. The positive predictive value varied little between algorithms A to D, ranging from 12% to 16%, and was considerably lower than for the observed 35% prevalence, ranging from 40% to 49%. The proportions of women who would be treated according to the algorithms if the prevalence of cervical infection was 10% were only slightly lower than for the observed prevalence of 35%.

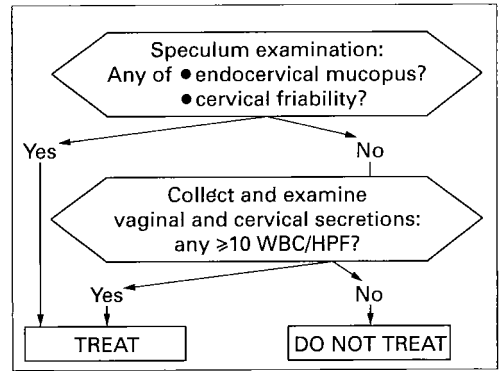
## Discussion

This study demonstrates that the search for valid diagnostic algorithms for cervical in-

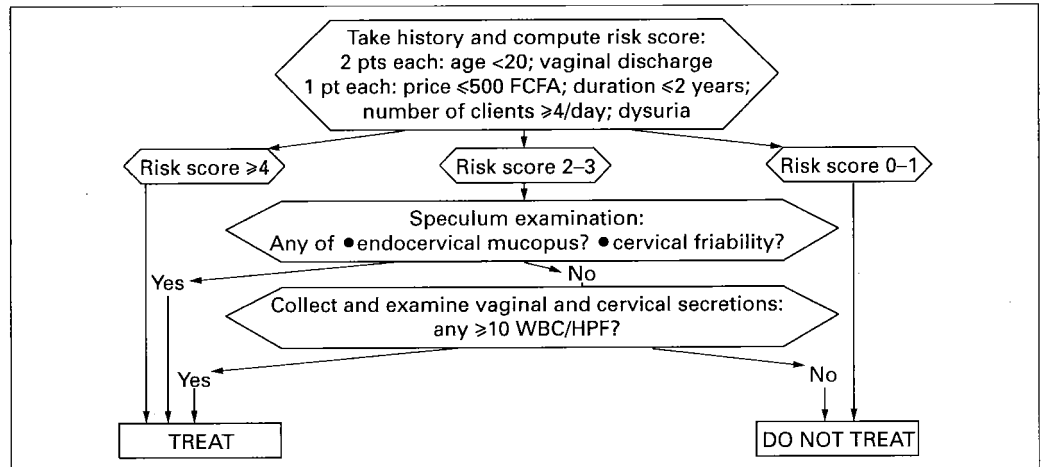
Algorithm A



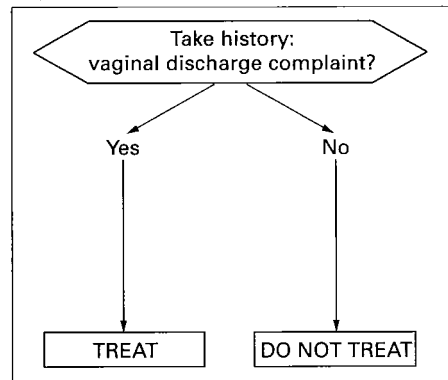
Algorithm B



Algorithm C



Algorithm D



Algorithm E

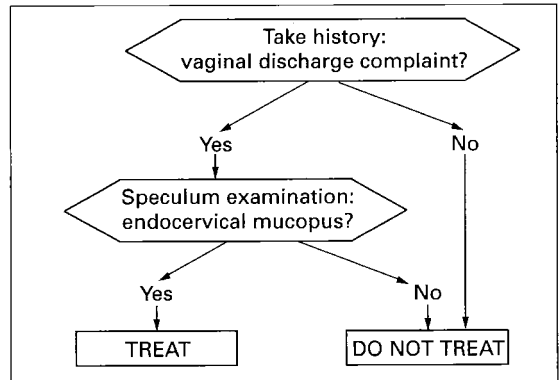


Figure 1 Data generated and modified WHO proposed simple algorithms for the diagnosis of cervical infection with *N gonorrhoeae* or *C trachomatis*. Algorithms A–C were generated from the data; algorithms D and E are modified from algorithms proposed by the WHO for use in symptomatic women (see Methods section).

fection with either *N gonorrhoeae* or *C trachomatis* that are independent of a sophisticated laboratory is challenging. An ideal diagnostic algorithm used for patient management would be both very sensitive and very specific, unlike a screening test which should be very sensitive but need not be very specific since a confirmatory test will be done for those who had a positive screening test. Given the prominent role of sex workers in spreading gonococcal and chlamydial infections, a high sensitivity of the algorithm may be more important than a high specificity, even if this implies that a considerable proportion of women would be treated inappropriately. This is acceptable from

a public health point of view as the number of sex workers is limited and the costs of antibiotics for overtreatment as well as the pressure for development of resistance to antibiotics would therefore be limited. Moreover, the cost of not treating a sex worker's cervical infection with *N gonorrhoeae* or *C trachomatis* may be considerable, as these infections have been implicated as facilitating both acquisition<sup>2,3</sup> and shedding<sup>12</sup> of HIV. All three generated algorithms (A–C) had a relatively high sensitivity but a low specificity, in contrast with the modified WHO proposed algorithms (D and E).

Only one previous study from sub-Saharan Africa has studied diagnostic algorithms for

cervical infection with either *N gonorrhoeae* or *C trachomatis* in female sex workers who do not necessarily report STD related symptoms.<sup>13</sup> In that study the decision to treat for *N gonorrhoeae* and *C trachomatis* was based on a risk score incorporating age and clinical signs. We took a similar approach to develop an algorithm that could be used without having to examine (A) and an algorithm that aims to reduce the number of examinations (C). While both of these algorithms had similar parameters of validity compared with a purely clinical algorithm (B), scores may not have the same validity across geographical and cultural areas and would therefore need to be validated in each area. The acceptability by medical and paramedical staff of score based diagnostic algorithms also needs evaluation.

The algorithms A–C were generated based on data from a population with a very high prevalence of cervical infection with *N gonorrhoeae* (31%) and *C trachomatis* (11%). Similar prevalence rates have been reported from other cross sectional studies in sub-Saharan Africa.<sup>26</sup> However, there is evidence that when female sex workers are counselled about condom use and screened and treated for STD, the prevalence of these conditions falls to lower levels.<sup>3</sup> A study among sex workers in Kinshasa showed that symptoms and signs that were associated with prevalent cases of cervical infection in a cross sectional study were also associated with incident cases of cervical infection in a longitudinal study.<sup>14</sup> Since in the present study the positive predictive values of the evaluated algorithms were much lower in a simulated population with a 10% prevalence of cervical infection than in a population with the observed 35% prevalence, a much larger proportion of women would be treated inappropriately in a population with a 10% prevalence. This is also apparent when comparing the 10% prevalence to the proportion of women that would be treated when applying the algorithms, ranging from 6% to 70%. This is in contrast with the comparison between the 35% prevalence and the proportion of women that would be treated, ranging from 9% to 73%. These comparisons suggest that if these algorithms were used in a control programme the proportion of women to be treated would remain stable and the proportion of inappropriately treated women would rise as the prevalence of cervical infection declines. The extreme case is represented by mass treatment where 90% of women would be inappropriately treated.

In the absence of simple, rapid, reliable, and inexpensive tests for the detection of cervical infections, targeted STD control programmes for sex workers in developing countries have to rely on algorithms, even though the above algorithms perform less than ideally. Considering the high prevalence of cervical infection among first time attenders, an algorithm with high sensitivity should be used in first time attenders, such as the above algorithms A–C or even mass treatment. For periodical screening visits in an STD control programme beyond the first visit, none of the studied algorithms is

clearly superior, since none of them combines a high sensitivity with a high positive predictive value in the 10% prevalence simulation. The choice of the diagnostic strategy may depend on the sophistication of the clinical setting and on the availability of funds for drugs, since the proportion of women to be treated according to the different strategies varies greatly.

Several studies among pregnant women in developing countries have evaluated diagnostic algorithms for cervical infection with either *N gonorrhoeae* or *C trachomatis*.<sup>13,15–17</sup> These algorithms have generally incorporated a risk assessment, based on sociodemographic and behavioural factors, such as age, having a new partner, being single or in a polygamous marriage, having multiple partners, or having a symptomatic partner. However, while among pregnant women many of these risk markers are better predictors of cervical infection than are symptoms or clinical signs, the validity of diagnostic algorithms for pregnant women that incorporate these risk markers remains disappointingly low. Many of these risk markers are not appropriate for female sex workers, who are at much higher risk of these infections than pregnant women. In agreement with a study on diagnostic algorithms for cervical infection with *N gonorrhoeae* and *C trachomatis* among female sex workers and pregnant women in Zaire,<sup>13</sup> the present study shows that among female sex workers clinical and biological factors are more strongly associated with cervical infection than sociodemographic and behavioural factors, and that a clinical algorithm (B) performs slightly better than a risk score algorithm (A).

In conclusion, the diagnostic algorithms evaluated in this study have considerable limitations. The search for simple, rapid, reliable, and inexpensive tests for the detection of *N gonorrhoeae* and *C trachomatis* remains a high priority for the control of cervical infections. In the meantime, however, the algorithms generated in this study may be useful for the control of cervical infections in female sex workers in resource poor settings.

Results were presented in part at the Tenth International Meeting of the International Society for STD Research, Helsinki, Finland, 29 August to 1 September 1993 (abstract no 67).

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