Clinical Algorithms for the Screening of Women for Gonococcal and Chlamydial Infection: Evaluation of Pregnant Women and Prostitutes in Zaire

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A substantial proportion of women with gonococcal and/or chlamydial infection are asymptomatic. Thus active case detection is problematical, particularly in developing countries, where facilities and materials for laboratory testing are limited. We assessed the diagnostic validity of the hierarchical clinical algorithms recommended by the World Health Organization as well as that of a nonhierarchical scoring system, using data for 1,160 pregnant women (a low-prevalence group) and 1,222 prostitutes (a high-prevalence group) in Kinshasa, Zaire. *Neisseria gonorrhoeae* and/or *Chlamydia trachomatis* was detected in 6.5% and 31.0% of pregnant women and prostitutes, respectively. No single variable that was both sensitive (>60%) and specific (>60%) was associated with infection. A simple hierarchical algorithm based only on reported symptoms had a sensitivity of 48.0% and 54.9% and a specificity of 75.2% and 52.2% for the screening of pregnant women and prostitutes, respectively. A second algorithm that included a speculum examination had a sensitivity of only 29.3% but a specificity of 85.3% in pregnant women. When a nonhierarchical scoring system was used, the sensitivity was 72.0% and 71.0% and the specificity was 73.5% and 55.8% for pregnant women and prostitutes, respectively. Scoring systems that incorporate risk markers as well as symptoms and signs may represent affordable alternative methods of screening for gonococcal and/or chlamydial infections among women in resource-poor settings.

Neisseria gonorrhoeae and *Chlamydia trachomatis* are two frequent causes of genital infections that have a major impact on health, particularly that of women and neonates. These infections have recently been shown to facilitate the sexual transmission of human immunodeficiency virus (HIV) [1]. Their serious complications include pelvic inflammatory disease, postpartum infection, ectopic pregnancy, and infertility [2–6]. Although early diagnosis and treatment could prevent these complications, a large proportion of gonococcal and chlamydial infections in women are asymptomatic, and many infected women fail to seek health care. Thus control strategies based on active case finding are needed [7–9].

Bacterial isolation techniques and immunologic methods for the detection of gonorrhea and chlamydial infection are expensive and are not widely available in developing countries. Diagnostic algorithms based on clinical signs and symptoms have been proposed by the World Health Organization (WHO) as a tool for better management of women who present with genital tract problems at the primary health care level [10]. It is not clear whether such algorithms can also be applied to case finding for sexually transmitted diseases (STDs) among women who present for reasons other than STDs—e.g., for antenatal care or family planning.

The objectives of this study were (1) to define variables that are predictive of gonococcal and chlamydial infections in women; (2) to assess the diagnostic validity of selected flow charts based on the WHO-recommended clinical algorithms as a screening tool for gonococcal and chlamydial infections in high- and low-risk populations in Africa; and (3) to assess a nonhierarchical decision system as a tool for case finding in the same populations.

Patients and Methods

Data collection. Data from cross-sectional surveys among two female populations in Kinshasa, Zaire, were used. The first study was conducted from March to August 1990 in four antenatal clinics, where 1,160 pregnant women were enrolled at random (every fifth woman) during their first antenatal visit. Demographic data, a sexual and medical history, and information on current urogenital symptoms were recorded by a nurse during a face-to-face interview. Speculum and gynecologic examinations were conducted by a physician, and a cervical swab test was performed [11].

Received 25 September 1992; revised 6 January 1993.

Financial support: This study was funded in part by the AIDS Task Force of the European Community Programme on Science and Technology for Development, the Rockefeller Foundation, and the American Foundation for AIDS Research.

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Clinical Infectious Diseases 1993;17:82–8

1058-4838/93/1701-0014$02.00

The second population studied consisted of 1,222 prostitutes seen at the Women's Health Center of Projet SIDA and enrolled in 1988 in a larger survey on STDs and HIV infection among female prostitutes in Kinshasa [12]. Interviews and clinical examinations were the same as for pregnant women except that the swab test was not done.

Laboratory procedures. Laboratory procedures were similar in the two surveys. A wet-mount preparation of a vaginal smear was examined microscopically by an experienced laboratory technician; *Trichomonas vaginalis* was sought, and the leukocyte count was determined. Gram-stained cervical smears (from pregnant women only) were examined for gram-negative diplococci and leukocytes. Endocervical swab samples were assayed for *N. gonorrhoeae* and *C. trachomatis.* Isolation of *N. gonorrhoeae* was attempted on modified Thayer-Martin medium in a candle extinction jar incubated at 36°C for 24–48 hours. Isolates were identified on the basis of typical colonial morphology, oxidase reaction, and gram stain result. *C. trachomatis* was detected in cervical specimens by an enzyme immunoassay (EIA; Chlamydiazyme; Abbott Laboratories, North Chicago, IL). A leukocyte-esterase dipstick (LED; Nephur-test; Boehringer Mannheim GmbH, Mannheim, Germany) was read for color change after immersion in midstream urine from each pregnant woman. Syphilis serology consisted of a rapid plasma reagin test (RPR test; Becton-Dickinson, Cockeysville, MD) and a *Treponema pallidum* hemagglutination test (TPHA test; Fujirrbio, Tokyo). HIV was assayed by EIA (Vironostika; Organon Teknika, Boxtel, The Netherlands), with a western blot (DuPont, Wilmington, DE) used for confirmation of positive results.

Definitions. Gonococcal/chlamydial cervicitis was defined by the presence of either organism. Because the two organisms cause similar symptoms and complications and are often associated, they were considered together. The diagnostic "gold standards" were isolation of *N. gonorrhoeae* and detection of *C. trachomatis* antigen, respectively. Women positive for either organism were designated "infected."

The LED method detects enzymes specific to polymorphonuclear leukocytes (PMNs); the results were semiquantified as <10 (0), ~10–25 (+), ~75 (++), or ~500 (+++) PMNs/μL of urine. A swab test was considered positive when yellow mucopurulent endocervical discharge was visible with the naked eye on a cotton swab. The presence of ≥10 PMNs per high-power field (hpf, 1,000×) in a gram-stained cervical sample was considered a positive result.

Evaluation of algorithms. WHO recommends algorithms or flow charts outlining the actions that should be taken by health care workers for the management of patients with STD-related conditions [10]. There are different protocols for any given syndrome or condition; the specific protocol followed depends on the laboratory facilities available. In this study, algorithms for two different levels of laboratory infrastructure were evaluated; these algorithms were based on the WHO algorithms for vaginal discharge and lower abdominal pain (figure 1). The first-level flow chart was designed for settings where facilities are limited (no examination table, gloves, or speculum) and the patient's symptoms ("vaginal discharge" or "lower abdominal pain") are the only basis for treatment. The other flow chart includes a speculum examination. Both flow charts are hierarchical, as the presence of vaginal discharge or abdominal pain is the limiting factor for entry. In contrast, a nonhierarchical system allows the consideration of several risk markers, signs, or symptoms at once and the calculation of a probability that the patient is infected.

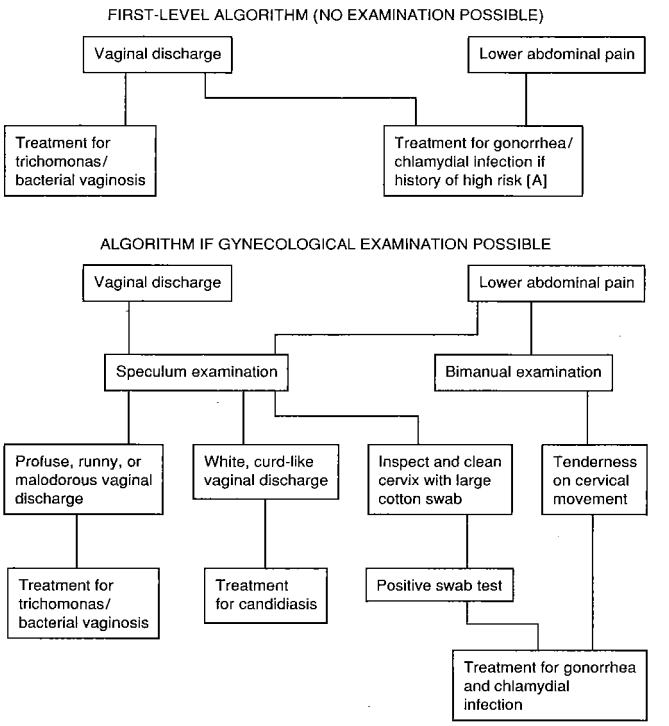

Figure 1. Hierarchical algorithms for vaginal discharge and lower abdominal pain, based on WHO algorithms. In the first-level algorithm, all prostitutes with vaginal discharge or lower abdominal pain were considered at risk. For pregnant women with these symptoms, those <25 years of age and those who were single or reported more than one sexual partner during the preceding year were considered at risk.

The algorithms were applied to the study populations in a simulation based on personal data from the interview and physical examination. The results of the simulation were compared with microbiological results. By this method we determined the number of true cases diagnosed by the algorithm (true positives), the number of women treated according to the algorithm (true plus false positives), the sensitivity of the model (number of cases detected/total number of infected women), the specificity of the model (number of negative women/total number of uninfected women), and the

positive predictive value of the model. It was not possible to evaluate the second algorithm for the population of prostitutes because the swab test was not done.

After the validity of these clinical algorithms had been determined, an alternative score-driven method was constructed (see below) and compared with the clinical approaches in terms of validity.

Statistical analysis and calculation of scores. In univariate analyses, the odds ratio (OR) was used for the measurement of associations. Proportions were compared by the χ^2 and Fisher's exact tests, means by Student's t test, and ordinal variables by the Wilcoxon rank-sum test.

Logistic regression was used to build a nonhierarchical quantitative decision system that took into account risk factors, symptoms, signs, and simple tests (independent variables) related to the presence of gonorrhea or chlamydial infection (dependent variable). The coefficients from the logistic regression analysis, multiplied by 10 and rounded to the nearest whole number, were used as scores in this system. The score in each case was the sum of the points for each variable present. The cutoff value above which the score was considered to be positive (resulting in a decision to treat) was chosen on the basis of a minimal sensitivity of 70% and a maximal positive predictive value when the score-based system was applied.

Results

Sociodemographic factors and prevalence of STDs. The two groups studied were comparable with regard to age (mean ± SD, 25.6 ± 6 years for pregnant women vs. 26.0 ± 7 years for prostitutes). Two-thirds of pregnant women were married or lived with one partner, whereas 20% reported having had more than one partner during the preceding year. The prostitutes had a mean (±SD) of 8 (±8) clients per week. At the time of the survey, the rate of condom use was very low (<10%). Overall, 89.4% of pregnant women and 88.6% of prostitutes had never used condoms. The prevalence of STDs except trichomoniasis was significantly higher among prostitutes than among pregnant women (table 1). Five percent of pregnant women and 35% of prostitutes were HIV-positive. Gonorrhea was detected in 1.6% and 23.4% of pregnant women and prostitutes, respectively; the corresponding figures for chlamydial infection were 5.2% and 13.0%, respectively. Seventy-five pregnant women (6.5%) and 379 prostitutes (31.0%) had gonococcal and/or chlamydial infection.

Parameters related to gonococcal and chlamydial infections. The relation of infection to risk factors, symptoms, clinical signs, and some simple laboratory tests, as assessed by univariate analysis, is shown in tables 2 and 3. Pregnant women with gonococcal and/or chlamydial infection were younger than uninfected pregnant women (mean age, 22.3 years vs. 25.8 years; $P < .001$). Other variables associated with gonorrhea and chlamydial infection included being single, having had more than one sexual partner over the preceding year, having vaginal discharge as a symptom or clinical sign or having vaginal itching as a symptom, having ≥10 PMNs/hpf in a cervical or vaginal smear, and having a positive LED test. The median LED test result was higher for infected than for uninfected pregnant women (++ vs. 0; $P < .001$).

Table 1. Prevalence of STDs among pregnant women and female prostitutes in Kinshasa, Zaire.

Finding	No. (%) with finding in indicated group: Pregnant women (n = 1,160)	Prostitutes (n = 1,222)
Antibody to HIV	56 (4.8)	433 (35.4)
Positive syphilis serology*	13 (1.1)	193 (15.8)
N. gonorrhoeae	19 (1.6)	286 (23.4)
C. trachomatis	60 (5.2)	159 (13.0)
N. gonorrhoeae and/or *C. trachomatis*	75 (6.5)	379 (31.0)
T. vaginalis	213 (18.4)	267 (21.8)
Genital ulcer	1 (0.1)	66 (5.4)

NOTE. The prevalence was significantly higher among prostitutes than among pregnant women for all STDs ($P = .001$) except trichomoniasis ($P = .038$).

* RPR and TPHA tests both positive.

Infected prostitutes were significantly younger than uninfected prostitutes (mean age, 23.9 years vs. 27.5 years; $P < .001$). No single symptom was associated with the presence of gonorrhea or chlamydial infection in this population. However, the combination of having more than three clients per week and having signs (including vaginal discharge, endocervical mucopus, cervical erosion, and cervical friability) was associated with infection.

In both groups, no single variable was both sensitive (>60%) and specific (>60%) for the presence of infection. Stratification of the women by the presence or absence of *T. vaginalis* (which was found frequently in both groups) did not influence these results (data not shown).

Evaluation of hierarchical algorithms. The results of the simulation with the hierarchical algorithms are summarized for the two groups of women in table 4. In settings where microscopy and speculum examination were not possible, the algorithm had a sensitivity of 48.0% and a specificity of 75.2% for the screening of pregnant women for gonococcal or chlamydial cervicitis; the corresponding figures for female prostitutes were 54.9% and 52.2%, respectively. The addition of a speculum examination and a swab test (studied with pregnant women only) greatly reduced the sensitivity of the diagnostic model to 29.3% but increased its specificity to 85.3%.

Nonhierarchical decision model. In an attempt to find al-

Table 2. Selected characteristics of pregnant women (n = 1,160) with and without gonococcal and/or chlamydial infection in Kinshasa, Zaire.

Characteristic	Percentage with finding in indicated group: Infected (n = 75)	Uninfected (n = 1,085)	OR	P
Risk determinants				
Age				
<25 y	74.6	48.1	11.2	<.001*
25–34 y	24.0	42.3	4.08	. . .
>34 y	1.3	9.6	1.00	. . .
Single status	46.7	21.0	3.30	<.001
>1 sexual partner in last year	49.3	18.1	4.41	<.001
Never having used condom	89.3	89.4	1.00	.855
Symptoms				
Vaginal discharge	36.0	22.0	1.99	.005
Dysuria	6.7	8.6	0.76	.565
Vaginal itch	29.3	19.2	1.75	.033
Lower abdominal pain	42.7	32.5	1.54	.071
Any of the above	60.0	46.5	1.73	.031
Signs				
Vaginal discharge	66.7	48.6	2.12	.002
Malodor	9.3	7.8	1.21	.641
Endocervical mucopus	1.3	0.7	1.80	.457
Cervical erosion	4.0	2.2	1.82	.414
Cervical friability	6.7	4.8	1.40	.414
Cervical motion tenderness	9.3	2.1	4.70	<.001
Any sign	72.0	51.8	2.39	.001
Results in simple tests				
LED test on urine				
~500 PMNs/μL	40.0	18.1	5.94	<.001*
~75 PMNs/μL	21.3	13.5	4.25	. . .
~25 PMNs/μL	18.7	14.8	3.37	. . .
<10 PMNs/μL	20.0	53.6	1.00	. . .
Swab test positive	52.9	29.4	2.69	<.001
Results of microscopy				
Leukocytes (≥10/hpf)				
Vaginal smear	73.3	49.0	2.86	<.001
Cervical smear	41.3	24.1	2.22	<.001
Gram-negative diplococci†				
Intracellular	21.1	0.6	42.82	<.001
Extracellular	63.2	8.2	19.13	<.001
Intra- or extracellular	68.4	8.4	23.59	<.001

NOTE. For dichotomous variables, only the percentages with positive findings are shown. For variables with multiple categories, the percentages are shown for each category, and an OR of 1 is assigned to the reference category.

* According to χ^2 for linear trend.

† Percentages are based on numbers of women infected with *N. gonorrhoeae* only.

ternatives to hierarchical algorithms starting with one or two limiting variables, we developed a scoring system that allowed the simultaneous consideration of multiple variables in the diagnostic approach. For pregnant women, a model that did not require clinical examination but that did include a LED test of urine was selected, since most clinical signs were not related to the presence of infection and since most simple laboratory tests require a speculum examination. The variables included in the logistic regression analysis and used to obtain a final score for these women are listed in table 5. All pregnant women with a score of >28 were considered infected.

The situation was different for the prostitute population, in whom only age and clinical signs were associated with infection. (LED testing was not performed.) The number of clients per week was no longer associated with infection after logistic regression analysis. Therefore, the variables included in the final logistic regression analysis were age and the clini-

Table 3. Risk factors, symptoms, and signs in female prostitutes (n = 1,222) with and without gonococcal and/or chlamydial infection in Kinshasa, Zaire.

Characteristic	Percentage with finding in indicated group: Infected (n = 379)	Uninfected (n = 843)	OR	P
Risk factors				
Age				
<20 y	26.1	15.2	3.74	<.001*
20–24 y	38.0	26.8	3.08	. . .
25–29 y	21.4	26.5	1.76	. . .
>29 y	14.5	31.6	1.00	. . .
>3 clients/w	79.4	73.8	1.37	.030
Never having used a condom	88.1	88.1	1.01	.972
Symptoms				
Vaginal discharge	27	23.1	1.23	.146
Dysuria	11.3	9.0	1.29	.208
Vaginal itch	32.7	31.9	1.04	.778
Lower abdominal pain	44.3	39.2	1.23	.094
Any of the above	65.2	59.5	1.27	.086
Signs				
Vaginal discharge	63.3	49.7	1.74	<.001
Endocervical mucopus	13.4	2.3	6.63	<.001
Cervical erosion	11.6	7.1	1.72	.009
Cervical friability	7.1	1.9	3.9	<.001
Cervical motion tenderness	10.2	10.1	1.02	.925
Any sign	69.7	56.2	1.79	<.001

NOTE. For dichotomous variables, only the percentages with positive findings are shown. For variables with multiple categories, the percentages are shown for each category, and an OR of 1 is assigned to the reference category.

* According to χ^2 for linear trend.

cal signs listed in table 5. All prostitutes with a score of >8 were considered infected according to this diagnostic model.

In both groups of women, the sensitivity of the score-driven method was much higher than that of the hierarchical algorithms (table 4). Although in pregnant women its specificity was slightly lower than that of either hierarchical algorithms, the score-driven method yielded a higher positive predictive value than those obtained with the WHO diagnostic models (table 4). The positive predictive value was also higher for the score-driven method than for the first-level algorithm when data from prostitutes were analyzed.

Discussion

In this study the association of the classic clinical symptoms and signs with the presence of gonorrhea and/or chlamydial infection was weak in both a high- and a low-prevalence population. No single sign or symptom reached an acceptable level of sensitivity and specificity combined.

In previous studies in industrialized countries, chlamydial infection among women has been associated with a relatively young age [7, 13, 14], with being unmarried [7, 8], and with either having had more than one sexual partner in the preceding 6–12 months or having a new sexual partner [7–9, 14]. An association between cervical infection and symptoms (including abnormal vaginal discharge and abdominal pain) has been identified in some studies [7, 13], but the association has more often been with clinical signs such as cervical ectopy, endocervical mucopus, cervical friability, or erythema [7–9, 11, 13–17]. Few data on infection with *N. gonorrhoeae* and/or *C. trachomatis* among women are available from developing countries.

Gonorrhea and chlamydial infection were considered together in our study, because they are the two main causes of cervicitis; they are associated with the same clinical symptoms, signs, and complications; and the strategies for their prevention and control are similar. In both of the populations we studied (pregnant women and prostitutes), we found that risk determinants such as age were more predictive of infection than were symptoms or clinical signs. Clinical signs like cervical mucopus or friability were specific, but their prevalence is so low that they are not very useful for screening. The coexistence of cervicitis and infection with *T. vaginalis* did not significantly alter the validity of symptoms and signs for the diagnosis of gonorrhea or chlamydial infection.

The rationale for LED testing of urine is based on the hypothesis that *C. trachomatis* is present in the urethra of a high proportion of infected women. Chernesky et al. found the organism in urethral cultures of 25 of 39 infected women (all with positive cervical and/or urethral cultures) among a total of 751 women studied [18]. Svensson et al. found urinary and urethral EIAs to have sensitivities of 84% and 57%, respectively [19]. The incorporation of simple tests like the LED test into a larger screening model could be interesting; these tests are practical, easy, rapid, inexpensive, and objectively interpretable. The same is not the case for demonstration of PMNs or gram-negative diplococci by gram staining; in fact, the latter tests are time-consuming and require a more specialized infrastructure.

The hierarchical algorithms, whether based on interview only or on interview plus clinical examination, were insensitive for the screening of both populations. Since the women who participated in these surveys did not come to the health center because of symptoms of STDs, the application of these algorithms can be considered to have represented case finding of gonococcal and chlamydial infection. In a clinic setting where women seek treatment specifically for STD-related conditions, the level of sensitivity of the algorithms may be much higher; this possibility should be evaluated. The reason for the poor performance noted in the low- and high-prevalence populations studied here is the low level of sensitivity of the starting symptom of the one variable–based algorithms. A score-driven system bypasses this limiting factor by simultaneously considering different variables (in-

Table 4. Diagnostic models for screening of women for gonococcal and/or chlamydial infections: results with pregnant women (n = 1,160) and female prostitutes (n = 1,222) in Kinshasa, Zaire.

	Result with indicated algorithm and group				
	First-level hierarchical*		Other hierarchical,†	Score-driven‡	
Parameter	Pregnant women	Prostitutes	pregnant women	Pregnant women	Prostitutes
No. of infected women	75	379	75	75	379
No. of cases diagnosed§	36	208	22	54	269
No. of women treated‖	305	611	182	342	642
Sensitivity (%)	48.0	54.9	29.3	72.0	71.0
Specificity (%)	75.2	52.2	85.3	73.5	55.8
Positive predictive value (%)	11.8	34.0	12.1	15.8	41.9

* Algorithm for vaginal discharge and lower abdominal pain in settings where speculum examination is not possible (see figure 1).

† Algorithm for vaginal discharge and lower abdominal pain in settings where speculum examination is possible (see figure 1).

‡ Model for pregnant women based on interview and LED test of urine, with cutoff point at 28; model for female prostitutes based on age and clinical examination, with cutoff point at 8 (see table 5).

§ Number of true cases diagnosed by the diagnostic model (true positives).

‖ Number of women treated when the diagnostic model was followed (false plus true positives).

cluding risk markers) instead of relying on one starting symptom. Other studies have also yielded better results when variables have been combined; however, these studies have considered chlamydial infections only and have been performed in industrialized countries [7–9].

The scoring system presented here was a simulation with which we investigated whether alternative approaches to the screening of women for gonococcal and chlamydial infection are at least theoretically possible. The scoring system needs to be evaluated in terms of field validity and feasibility in different settings and also with regard to reproducibility in the same population and generalization to other populations. We found that risk profiling is valid for pregnant women but that, in a high-risk population like prostitutes, the model should be based on other variables, such as simple laboratory tests. The applicability of the hierarchical algorithms in a variety of settings is a matter of concern. Speculum examination may appear very simple, but it is time-consuming and is not always possible in primary health care centers or prenatal clinics. In the score-driven method for the evaluation of pregnant women, five questions and LED testing of urine were sufficient. This approach is feasible and economically acceptable in most situations but may require substantive training of health care workers.

Table 5. Scores used in the score-driven diagnostic model for infection with *N. gonorrhoeae* and/or *C. trachomatis* in women.

Group, variable	Score
Pregnant women*	
Single status	5
>1 partner in last year	10
Age <25 y	14
Age 25–34 y	11
Report of vaginal discharge	1
Report of lower abdominal pain	3
LED testing of urine†	
+	10
++	12
+++	15
Female prostitutes‡	
Age <20 y	13
Age 20–24 y	10
Age 25–29 y	5
Finding on physical examination	
Vaginal discharge	3
Cervical mucopus	17
Cervical friability	9

* Pregnant women with a total score of >28 were considered infected.

† Scoring: + = 10–25 PMNs/μL; ++ = ~75 PMNs/μL; and +++ = ~500 PMNs/μL.

‡ Prostitutes with a total score of >8 were considered infected.

The score-driven method used in this study was based on the log of the OR for each variable included in the model. Previously described scoring systems have generally been based on the log of the likelihood ratios [20] but have been used to identify the subsample of patients to whom specific diagnostic tests were applicable. Our approach tends to give more weight to variables highly associated with the presence of disease. This approach may be particularly appropriate when the score is used by itself to make the final diagnosis.

Screening for gonococcal and/or chlamydial cervicitis remains a major challenge in women's health care. The commonly used WHO diagnostic algorithms may be useful for symptomatic women in general consultations or in STD clinic settings, but they are not sensitive enough to be used as

a screening tool. Through the incorporation of various risk determinants, symptoms, signs, and simple laboratory tests into a score-driven method, sensitivity can be improved but specificity remains rather low. Thus further work on uncomplicated clinical-decision approaches and on simple, rapid, cheap tests useful for diagnosis of gonorrhea and chlamydial infection in women remains a high priority.

Acknowledgments

The authors are indebted to Dr. M. Luyeye and the Staff of Projet "Santé Pour Tous" in Kinshasa and to the staff of the laboratory of Projet SIDA for their cooperation and support. The investigators also thank Karin Janssens for typing the manuscript.

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